S. Hrg. 101-964

FISH INSPECTION: PENDING LEGISLATION REGARDING MANDATORY SEAFOOD INSPECTION PROGRAMS

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

THE FEDERAL FISH INSPECTION ACT AND A MANDATORY SEAFOOD INSPECTION PROGRAM

OCTOBER 24, 1989

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry

U.S. GOVERNMENT PRINTING OFFICE
35-214 ⇆ WASHINGTON : 1990

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

S161-3

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FISH INSPECTION: PENDING LEGISLATION REGARDING MANDATORY SEAFOOD INSPECTION PROGRAMS

TUESDAY, OCTOBER 24, 1989

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 2:30 p.m., in room SR-332, Russell Senate Office Building, Hon. Patrick J. Leahy (chairman of the committee) presiding.

Present or submitting a statement: Senators Leahy, Harkin, Daschle, Lugar, Cochran, Bond, and Gorton.

STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

The CHAIRMAN. I understand that Senator Mitchell is on his way over from the caucus. Partly because of the time constraints this afternoon, and knowing that each of the witnesses only has a few minutes, I will put my opening statement in the record prior to other Senators coming, so that we can start the hearing.

In recent months, if you read the news, we find a number of stories that have raised questions about the safety of our food.

We have seen apples that have been sprayed with Alar. We have seen grapes from Chili tainted with cyanide and fish found with chemical and pesticide residue. Those are only a few of many, many food safety problems that have been reported.

Food safety is not just a media issue. American consumers are concerned and worried. I hear it not only when I am back in Vermont but when I hold hearings all over the country. I have said many, many times that America produces the safest food in the world, but we can certainly do a lot better.

Seafood, for example, is the only flesh food not subject to mandatory Federal inspection in this country. The existing voluntary, industry-based programs are used on only 11 percent of our seafood. Only 7 percent of the almost 2,000 seafood processors participate in these voluntary inspection programs.

I believe that we need to have a mandatory seafood inspection program. We need that just to maintain the consumer confidence that this country requires if we are going to be able to sell our products. We cannot continue with the status quo as some in the administration would like. So the hearing today will be on the basis of trying to get a mandatory seafood inspection program.

And it will be because I have heard from Senators on both sides of the aisle that they are not willing to put up with the status quo. Consumers themselves have already sent a very strong message to us. Fish consumption was at an all time high in 1987. It fell in 1988 for several reasons, one, the primary one, was consumer food safety concerns.

We should not delude ourselves. Mandatory Federal inspection cannot completely eliminate all the contaminants from the marketplace. In fact, if you have a sterile product, one that leaves the processor perfectly safely, and it is mishandled by the consumer, it can still create problems. But a mandatory inspection program will make our seafood safer and reduce the risk of illness to consumers. It will at least start the chain off with a safe product.

The purpose of this hearing is to help us develop legislation that provides such a program—but without dismantling the seafood industry. In that regard, I am going to work closely with all concerned, with the consumer groups, with the seafood industry, State government and with Federal agencies.

Fortunately, both industry and the major consumer organizations agree that we should do something, and I wish to commend both leaders from the consumer groups and from the industry who have worked so hard together. I do not expect them to agree on every single point by any means, but the fact that they have worked very closely together means it is going to be easier for those of us around this table to reach agreement.

As I have found in talking with both the industry and the consumer groups, they both believe that we should have a program, that it should be operated by the Department of Agriculture, that it should include Good Manufacturing Practices, that it should ensure the quality of imported products, and that it should prevent economic fraud.

Unfortunately, the administration has not seen fit to make a decision.

We have known both the industry's and the consumer's position on this issue for months. Yet the Department and the administration has been unwilling and unable to make a decision. I quote from Mr. Brennan's testimony, "Whether or not to establish an expanded inspection program, or which agency should administer such an expanded program if the Congress were to establish one, is an issue currently under review by the Administration."

Well, when you say "under review" we find that is shorthand here. "Under review" means we cannot make up our mind.

Well, nearly a full quarter of the Senate has made up its mind. Senators Mitchell, Cochran, and I, along with 20 other Members, have already introduced or cosponsored legislation, S. 1245, calling for a mandatory program. I intend to introduce legislation myself in the near future as an amendment to S. 1245 to flesh out some of the ideas.

I do not want to put together and go through all this work to get something that gives just the appearance of an inspection system. I want something that consumers can look at and say that is something we have confidence in. That really is good inspection legislation. The industry, consumer groups, everybody else can go out and say you can have a sense of reliance in this program. Now, hopefully, before we get done, the administration will make up their mind. If they do not, then we will just do it.

I feel very much that the program belongs within the Department of Agriculture. The Food and Drug Administration, the National Marine Fisheries Service, as well as others, can and should contribute ideas on how to operate such a program. But I believe the legislation that will come out of this committee will put it within the Department of Agriculture, and this is not the hearing to decide that point.

We have a lot of work to do on this issue. We have disagreements on everything from what type of vessels and how they are used to how you protect whistleblowers. But if we remember first and foremost that there is an awful lot more we agree on today than most people thought was possible a year ago, we are going to get somewhere.

Senator Gorton, did you have anything you wanted to say? They do not do any fishing out your way, do they?

Senator GORTON. I have listened to your comments, Mr. Chairman, and I simply wish to endorse them. I think that your original bill is a move in exactly the right direction, and I look to hearing from the witnesses as to how we can best and most successfully accomplish it, both for the industry and for the consumer.

The CHAIRMAN. Thank you.

[The prepared statement of Senator Leahy and the prepared statement of Senator Lugar, with responses to questions submitted by Senator Lugar on fish inspection to Jo Ann Smith, Assistant Secretary, follow:]

PREPARED STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

In recent months, the evening news has been filled with stories raising questions about the safety of our food.

Apples sprayed with Alar, grapes from Chile tainted with cyanide and fish found with chemical and pesticide residue are among the food safety problems reported.

Food safety is not just a media issue. American consumers are concerned and worried. Although America produces the safest food in the world, we can do better. We must protect our consumers and make certain that the food in the market is safe and nutritious.

Clearly a mandatory program is needed to maintain consumer confidence. We cannot continue with the status quo as some in the administration would like. The consumer has already sent a strong message. Fish consumption was at an all time high in 1987. It fell in 1988 for several reasons, one was consumer concern.

Seafood is the only flesh food not subject to mandatory Federal inspection. Existing voluntary, industry-based programs are used on only 11 percent of our seafood—and these are designed more for grading product than for ensuring safety. Only 7 percent of the almost 2,000 seafood processors participate in these voluntary inspection programs.

Imported product has the potential to be even more of a problem. In 1986 alone, a mere 5 percent of the 167,000 shipments of imported seafood were inspected at the wharf; the rest were waived though.

Seafood must be inspected because uninspected fish and shellfish may be contaminated by polluted waters, parasites and disease. Twenty percent of all reported foodborne illnesses are caused by contaminated seafood.

We should not delude ourselves. Mandatory Federal inspection cannot completely eliminate all contaminants from the marketplace. Even a sterile product, when mishandled can cause a problem. But a mandatory inspection program will make our seafood safer and reduce the risk of illness to consumers.

The purpose of this hearing is to help us develop legislation that provides such a program—but without dismantling the industry. I intend to work closely with all concerned, consumers, industry, State government and Federal agencies. We cannot put together a program that just gives the appearance of an inspection system. We need a strong program to restore and keep the consumer's confidence.

Fortunately, the industry and major consumer organizations are in agreement on a number of points. I commend both groups that are with us today for their willingness to work on this issue.

Both believe that:

—We should have a program;
—That it should be operated by USDA;
—That it should include Good Manufacturing Practices;
—That it should ensure the quality of imported products; and
—That it should prevent economic fraud.

The list goes on. In fact I'd say that the two "sides"—if you can call them sides—on this issue are probably in agreement on 70-80 percent of what should be in the program.

Unfortunately, the administration has not seen fit to make a decision.

We have known both the industry's and the consumer's position on this issue for months. Yet to quote from Mr. Brennan's testimony, "Whether or not to establish an expanded inspection program, or which agency should administer such an expanded program if the Congress were to establish one, is an issue currently under review by the Administration."

Frankly I don't understand why they cannot make a decision.

A full quarter of the Senate has made a decision. Senators Mitchell, Cochran, and I, along with 20 other Members, have already introduced or cosponsored legislation—S. 1245—calling for a mandatory program. I intend to introduce legislation myself in the near future as an amendment to S. 1245 that will serve to flesh out some of the ideas contained in S. 1245.

Almost everyone here agrees with industry and consumers in saying that this program belongs with USDA. The Food and Drug Administration, the National Marine Fisheries Service, as well as others, can and should contribute ideas on how to operate such a program. I want to hear from them and welcome the opportunity to receive their testimony. But I want all of us to understand where I think it belongs—within USDA.

We have a lot of work to do on this issue. I do not want to downplay the items that are in disagreement from how we handle vessels to whistleblower protection. But as long as we can all remember how much we already agree on, I am hopeful we can move legislation in this Congress.

PREPARED STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Mr. Chairman, I am pleased to join you today as a cosponsor of the legislation being reviewed today and to comment on its merits.

I believe this legislation establishes the appropriate parameters for a Federal fish inspection program. An inspection system will be developed for fish and fish products that carries with it the assurance of quality consumers have in other USDA inspection programs. Consumers need a system in which they are assured of food safety and quality. As consumer awareness continues to increase, so do demands for assurances of product safety and wholesomeness. We have successfully met these demands in the meat and poultry area and need to strive for the same confidence in seafood.

In addition, our Nation is served by a seafood industry of various sizes, services and locations. For several States, this is one of their largest industries and therefore any legislation must be representative of their needs. Several States have already developed their own inspection program and it is important to recognize these efforts and coordinate already established State programs into the Federal program.

I am especially interested in the development of this program on an international basis. Imported fish and fish products must be inspected in order to assure wholesomeness of all products. USDA's inspection network is well established abroad and can be implemented immediately.

I commend the consumer and industry groups for working together to create a Federal fish inspection discussion. I look forward to hearing their comments concerning this legislation.

In reference to the legislation, I asked the Department of Agriculture to respond to several questions. I would ask that these questions and the Department's responses be entered into the record.

[The questions and responses follow:]

RESPONSE TO QUESTIONS ON FISH INSPECTION

Question 1. What components do you see as essential to your existing inspection programs that you would include in the seafood inspection program? What would you have to put in place to establish a seafood inspection program?

Answer. Except for inspection of individual fish, nearly all elements of the current meat and poultry inspection program are essential for a seafood inspection program. For example, inspection officers would be needed for the inspection of fish processing vessels and plants, compliance officers would be needed for ensuring adherence to fish inspection laws, laboratories and scientists would be needed to conduct analyses, labeling standards must be established, inspection of imported and exported fish products, etc. In short, a program modeled after the meat and poultry inspection system would ensure coverage of most of the potential problem areas in a fish inspection program.

One exception, however, that would require expansion from the current meat and poultry inspection program would be the use of the Hazard Analysis and Critical Control Point (HACCP) for fish inspection. USDA's Food Safety and Inspection Service (FSIS) has already incorporated HACCP procedures into certain aspects of current inspection operations, and is making plans for a full implementation of HACCP into other areas of processing inspection.

It is widely agreed that HACCP is particularly well-suited to fish and seafood inspection. HACCP involves a prioritization of the potential risks and an increased emphasis on the "critical control points." A critical control point is a point where failure to control the process is likely to result in the manufacture of an unsafe or otherwise violative product. As mentioned above, FSIS has experience with HACCP in meat and poultry, but additional experience and resources will be needed if a fish inspection program is to be totally based on HACCP.

Another area where additional resources and cooperation will be necessary is in the inspection of fishing waters. Currently, FSIS authority over meat and poultry begins at the slaughterhouse. An extension of that authority in a fish inspection program back to fishing waters may be best handled by cooperative agreements with States of other Federal agencies.

Additionally, FSIS would need to become familiar with any particular hazards or diseases associated with seafood that are not normally associated with meat or poultry. While many of the hazards and diseases may be similar for seafood and meat and poultry, any differences would need to be incorporated into the training program for FSIS inspectors.

Question 2. A crucial part of our existing inspection programs is our work with imported seafood. Explain how FSIS in its International and Special Programs Division interact with American embassies, and their functions overseas. Can this be adapted to inspection of imported fish products as well?

Answer. FSIS routinely conducts reviews of foreign meat and poultry inspection systems and processing facilities to assure U.S. standards are maintained. In addition, FSIS certifies the safety and wholesomeness of U.S. meat and poultry products that are exported.

These activities require FSIS to maintain regular contacts with foreign inspection officials to exchange information, schedule on-site review visits and resolve product certification problems. The need to assure that foreign inspection systems, which are eligible to export to the United States continually, meet U.S. requirements means that FSIS must regularly obtain inspection reports on a variety of activities from foreign inspection officials.

FSIS technical staff conduct on-site reviews at least twice each year in each eligible exporting country. The Foreign Agricultural Service (FAS) and State Department officials at American Embassies assist FSIS by passing official correspondence between foreign inspection officials and FSIS and providing travel support for onsite reviews by assisting with arrangements and providing translation services when needed. Further, these embassy officials act as U.S. spokespersons in diplomatic situations, thereby buffering FSIS technical reviewers from nontechnical matters.

FSIS conducts a certification program for meat and poultry products exported to foreign countries. This program, which has been in operation since 1981, assures the safety and wholesomeness of U.S. products. Occasionally, certificate errors occur and must be corrected rapidly to avoid loss of product. The FAS agricultural counselors and attachés provide assistance to FSIS by notifying FSIS of problems and transmitting corrections to foreign inspection and customs officials.

We believe the established procedures used by FSIS to assure the safety and wholesomeness of imported and exported meat and poultry products—including interactions with American Embassy officials—would be beneficial to the seafood industry.

Question 3. Can you expand on the type of training done at your FSIS training center in Texas and how the programs can be adapted to fish inspection?

Answer. FSIS has always provided extensive training and continuing education for its inspectors. FSIS has had a goal of formally training all members of the inspection force since the first training stations were established in 1964.

On April 3, 1989, FSIS opened a new Training Center at Texas A&M University at College Station, Texas. The move allowed the scientific and technical content of the training courses to be increased without deleting any material taught at earlier FSIS training centers. Specialized education is offered in food chemistry, risk analysis, veterinary pathology, statistics, and computer science. About 45 percent of the trainees' instructional contact is with university faculty and 55 percent with FSIS instructors.

Training is a continual process within FSIS. Among those receiving instruction at the Training Center are new hires, inspectors transferring from slaughter to processing inspection, and new supervisors. Also trained are food technologists, who are either newly hired or FSIS food inspectors who have upgraded their skills. FSIS has been training about 100 food technologists a year, in order to place them into complex processing assignments. Early projections call for about 1,900 employees to receive training at College Station in 1991.

Texas A&M has a number of resources available to support training in fish and seafood inspection. For example, the Galveston Campus contains the marine and maritime component of the university, and offers degree programs in marine biology and marine fisheries, among others. The university also has adjunct professors who are experts in aquatic food safety and seafood technology. Texas A&M's College of Veterinary Medicine includes studies in the microbiology, public health, toxicology, mycotoxicology, and epidemiology of aquatic and marine species.

Further, the university's Department of Wildlife and Fisheries Sciences has a faculty of 25 that is very active in research on fish and seafood. The location of the Veterinary Medical Diagnostic Laboratory of Texas on the campus would also be of assistance to a fish inspection program.

Question 4. There is high visibility and consumer confidence in the USDA seal and labeling program. What aspects of this program can be adapted to fish and fish products?

Answer. We believe a labeling program similar to FSIS' would help reduce the confusion among consumers of fish and seafood as to exactly what they are purchasing, as well as to help prevent fraudulent practices.

The most important aspect of the current FSIS labeling program that should be adapted to a fish inspection program is the reviewing of labels prior to allowing their use. Label approval applications must include the product name, formula, method of preparation, type of container, and how the label is to be used.

A number of labeling requirements apply across-the-board to all meat and poultry products. These include: appropriate product name; ingredients used listed by weight from most to least; net quantity of the package contents; name and address of the manufacturer, packer, or distributor; the USDA mark of inspection; and any special care of handling instructions, such as "keep refrigerated." In addition, any aspect of labels, including photographs or artwork depicting a product must not be false or misleading. All of these requirements could and should be adapted for fish and seafood products.

Question 5. Several States have existing State seafood inspection programs. What are your thoughts on these programs and how they should apply to a national inspection program?

Answer. We recognize that many States already have fish inspection programs in place, and we believe it is crucial to work with those States to ensure there is no duplication.

Our experience of Federal-State cooperation in meat and poultry inspection would be beneficial in establishing a similar setup for fish inspection. FSIS conducts a unique Federal-State meat and poultry inspection program that provides 50 percent program funding to States if their inspection programs are at least equal to Federal standards. Currently, 28 States have their own meat and poultry inspection programs.

Question 6. What process does FSIS go through to approve plants for inspection?

Answer. Meat and poultry plants must apply for approval to operate and to receive an inspection number to be under FSIS inspection. Prior to being granted Federal inspection, meat and poultry plant facilities and equipment are approved to ensure products will be produced in a clean and sanitary environment. Extensive and rigorous standards have been implemented and are strictly enforced both before and after inspection has been granted.

Question 7. Do some of the plants you now regulate process fish products?

Answer. Yes. FSIS does have a cross-utilization agreement with the National Marine Fisheries Service (NMFS), whereby FSIS provides inspection services to the NMFS voluntary fish inspection program. Prior to performing this inspection, FSIS inspectors are trained by the NMFS. Since FSIS inspectors have already received training in food technology areas such as microbiology, quality control, HACCP, etc., approximately 4 hours of NMFS training is all that is needed for FSIS inspectors to perform inspection on fish and seafood products.

Question 8. Can you expand on the laboratory analyses that your agency does to protect public health?

Answer. FSIS has 3 in-house laboratories located at Alameda, CA, St. Louis, MO, and Athens, GA, 2 contract laboratories, and 315 accredited private laboratories. All have extensive experience analyzing for chemical residues, microbiological contamination, processed product composition, and economic adulteration.

Since 1967, FSIS has developed an annual National Residue Plan with the goal of preventing illegal residues of drugs, pesticides, and environmental contaminants in meat and poultry. FSIS meets this goal primarily through a statistically based sampling and testing program that monitors trends and identifies problem areas. Laboratory analyses are the key to this sampling and testing program.

Each day, a statistically based selection of random samples are taken from healthy-appearing animals brought in for slaughter at meat and poultry plants around the country. These samples are then sent to the laboratory for analysis. The results are usually reported within 8 days. These results enable FSIS to report a nationwide, statistically based violation rate for over 120 different compounds. The system is designed to provide a 95 percent assurance that a violation will be found even if it occurs in only 1 percent of meat or poultry slaughtered under Federal inspection.

Generally, the residue violation rate is quite low—less than 1 percent. If we find there is a problem, however, we will move to a biased sampling program referred to as surveillance testing. Surveillance testing is directed at particular carcasses or products. In-plant testing procedures may be performed by the inspector, or samples may be submitted to the laboratory for analysis.

Question 9. Can you briefly discuss how USDA implemented the more recent inspection programs which had been enacted by Congress?

Answer. Up until 1957, poultry inspection was done on a voluntary basis, just as fish inspection is done today. In the late 1950's, Congress enacted legislation mandating poultry inspection and combining it with the mandatory meat inspection program. Congress also authorized the establishment of State meat and poultry inspection programs, provided State programs are at least equal to Federal standards. The 50/50 Federal-State funding agreement was also part of this congressionally mandated system.

The CHAIRMAN. What I would do is call the panel, Jo Ann Smith, Assistant Secretary of Agriculture for Marketing and Inspection Services from the Department of Agriculture; Frank Young, the Commissioner of the Food and Drug Administration; and James Brennan, the Deputy General Counsel of the National Oceanic and Atmospheric Administration as part of the first panel.

And I might say to the panel, to Mrs. Smith and Dr. Young and Mr. Brennan, that if at some point, because of the schedule on the floor, Senator Mitchell is able to join us, I hope you will not mind if we temporarily interrupt you and let Senator Mitchell testify. That is a matter of courtesy because of his interest in this area, and secondly, he is the Majority Leader, and neither Senator Gorton nor I want to find our offices down in Union Station. It has something to do with the seniority system around here.

I will start off with Mrs. Smith and then Commissioner Young and then Mr. Brennan. Mrs. Smith.

STATEMENT OF JO ANN SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC, ACCOMPANIED BY DR. LESTER CRAWFORD, ADMINISTRATOR OF THE FOOD SAFETY AND INSPECTION SERVICE; AND DR. CATHERINE ADAMS, FOOD SCIENTIST AND REGISTERED DIETITIAN

Mrs. SMITH. Thank you.

Mr. Chairman, on behalf of the U.S. Department of Agriculture, I appreciate this opportunity to testify today on S. 1245, a bill to establish a comprehensive fish inspection program.

I have with me Dr. Lester Crawford who is the Administrator of the Food Safety and Inspection Service; and Dr. Catherine Adams, whose specialty is food science and is also a registered dietitian.

CONSUMERS ARE LOOKING FOR A PROGRAM THAT WILL ASSURE THEM THAT THE SEAFOOD THEY EAT IS SAFE, WHOLESOME, AND PROPERLY LABELED

Consumers are looking for a program that will assure them that the seafood they eat is safe, wholesome, and properly labeled. Many consumers might be surprised to learn that most seafood currently is not under mandatory inspection. Up until 1956, a voluntary fish inspection program under the Agricultural Marketing Act was located at USDA. The voluntary program is now operated by the National Marine Fisheries Service under the Department of Commerce.

DISCUSS HOW THE U.S. DEPARTMENT OF AGRICULTURE MIGHT BE ABLE TO IMPLEMENT A MANDATORY FISH INSPECTION PROGRAM

With the understanding that the administration still has the issue under review, I would like to discuss today how the U.S. Department of Agriculture might be able to implement a mandatory fish inspection program that would provide those assurances to consumer.

NOT A NEW EXPERIENCE

Mr. Chairman, the experience of incorporating and administering a new inspection program would not be new to FSIS. Years ago, after the voluntary poultry inspection program was made mandatory by Congress, the agency successfully combined the separate meat and poultry inspection programs into a single, strong inspection system.

The CHAIRMAN. As I suggested earlier, Mrs. Smith, if I could ask you just to hold for a moment. I mentioned, Mr. Leader, that you have a busy schedule on the floor, and that you would be cutting in, and we do this out of respect for the schedule and the fact that none of us want our offices switched to Union Station. [Laughter.]

STATEMENT OF HON. GEORGE J. MITCHELL, SENATE MAJORITY LEADER, A U.S. SENATOR FROM MAINE

Senator MITCHELL. Well, I thank you very much, Mr. Chairman. Mrs. Smith, I thank you and apologize for the inconvenience to you by this interruption.

One of the reasons I like to appear before this committee is rarely do I get so close to the chairman during my testimony as I do here. So I begin, Mr. Chairman, by thanking you for the opportunity to testify as well as your leadership on the issue of Federal fish inspection, along with that of Senator Cochran, Senator Lugar and others.

S. 1245 IS SPONSORED BY 25 MEMBERS

When Senator Cochran and I introduced S. 1245 on June 22, we were joined by 11 cosponsors, including the chairman and Ranking Republican Member of this committee. The legislation today is sponsored by a total of 25 Members of the Senate, almost double its original number.

This is a bipartisan issue. It is tremendously important both to the American consumer and to States, such as Maine, with substantial commercial fishing industries. I am especially grateful to groups such as the Associated Fisheries of Maine, the Maine Sardine Council, and the Maine Fishermen's Cooperative Association, who have encouraged the effort for this legislation.

WHATEVER AFFECTS THE CONFIDENCE OF CONSUMERS IN THE SEAFOOD MARKET, ULTIMATELY AFFECTS THE LIVELIHOODS OF MANY

Whatever affects the quality of seafood, and whatever affects the confidence of consumers in the seafood market, ultimately affects the livelihoods of many, many Maine fishermen and their families. If a Federal fish inspection program is to be established, it is important to the State of Maine and our fishermen that it be done right.

COSPONSORS TO WORK WITH ALL INTERESTS

In introducing this bill (S. 1245), I stated the intention of the bill's cosponsors to work with all interests first to define, and then to refine a consensus for a Federal fish inspection program.

S. 1245 IS A CONSENSUS BILL

S. 1245 is a consensus bill. It is a starting point. It contains provisions supported by both consumer interests and the commercial fishing industry. It is the only bill that has been introduced in the Senate at this time. I understand, Mr. Chairman, that you intend to introduce an additional bill that will identify certain issues—which are likely to be the subject of key amendments or compromises during the committee's eventual markup of this legislation.

S. 1245 OFFERS THE MOST BROADLY SUPPORTED, MOST COMPELLING FEATURES

In the House of Representatives, there currently are six different bills, each offering variations on the single theme: that a comprehensive, effective Federal fish inspection program is needed. S. 1245 offers the most broadly supported, most compelling features for such a program. It includes the following key provisions:

KEY PROVISIONS

The Department of Agriculture shall be responsible for Federal fish inspection.

The Federal Government shall fund the program directly as a public health program; it must not be funded through any system of industry user fees.

The program's inspections and standards should be based on the Hazard Analysis Critical Control Point (HACCP) method.

Imported fish products must be subject to the same standards as the domestic industry.

COOPERATION

The Federal program must include cooperation between the Department of Agriculture and other Federal agencies, as well as the States.

Mr. Chairman, I ask unanimous consent that the full text of my prepared statement be placed in the record, as I have to be back on the Senate floor within just a few minutes. I thank you and our colleagues on the committee and the other witnesses for the courtesy in permitting to testify out of turn.

The CHAIRMAN. Mr. Leader, we appreciate your coming over here and we appreciate the help that you have given in working to get both consumer representatives and the industry representatives together on what is a major issue. I think that the kind of cooperation that we have seen in those two sectors bodes well for good legislation, and we will try to get together something that can come out of this committee in as strong a bipartisan fashion as possible and with as much support as possible so that we can then come to you and say we are ready to go on the floor.

Senator MITCHELL. I await that day enthusiastically, Mr. Chairman. I want to especially thank Senator Cochran, who is the original cosponsor with me of this bill. It has been a pleasure to work with him, and I look forward to continuing that effort until we get it enacted into law. Thank you again.

[The prepared statement of Senator Mitchell follows:]

PREPARED STATEMENT OF HON. GEORGE J. MITCHELL, SENATE MAJORITY LEADER, A U.S. SENATOR FROM MAINE

Mr. CHAIRMAN. Thank you for the opportunity to testify before the committee—as well as your early leadership on the issue of Federal fish inspection, along with that of Senator Cochran and Senator Lugar.

When Senator Cochran and I introduced S. 1245 on June 22, we were joined by 11 cosponsors, including the chairman and Ranking Republican Member of this committee. The legislation today is sponsored by a total of 25 Members of the Senate, almost double its original number.

This is a bipartisan issue. It is tremendously important both to the American consumer and to States, such as Maine, with commercial fishing industries. I am especially grateful to groups such as the Associated Fisheries of Maine, the Maine Sardine Council, and the Maine Fishermen's Cooperative Association, who have encouraged the effort for this legislation.

Whatever affects the quality of seafood, and whatever affects the confidence of consumers in the seafood market, ultimately affects the livelihoods of all Maine fishermen. If a Federal fish inspection program is to be established, it is important to the State of Maine that it be done right.

In introducing S. 1245, I stated the intention of the bill's cosponsors to work with all interests first to define, and then to refine a consensus for a Federal Fish Inspection Program.

S. 1245 is a consensus bill. It is the starting point. It contains provisions supported by both consumer interests and the commercial fishing industry. It is the only bill that has been introduced in the Senate at this time. Senator Leahy intends to introduce an additional bill that will identify certain issues—which are likely to be the subject of key amendments or compromises during the committee's eventual markup of S. 1245.

In the House of Representatives, there currently are six different bills, each offering variations on the single theme: that a comprehensive, effective Federal fish inspection program is needed. S. 1245 offers the most broadly supported, most compelling features for such a program. It includes the following key provisions:

- The Department of Agriculture shall be responsible for Federal fish inspection.
- The Federal Government shall fund the program directly as a public health program; it must not be funded through any system of industry user fees.
- The program's inspections and standards should be based on the Hazard Analysis Critical Control Point (HACCP) method.
- Imported fish products must be subject to the same standards as the domestic industry.
- The Federal program must include cooperation between the Department of Agriculture and other Federal agencies, as well as the States.

I want to focus today on the first point: that the program be placed in the Department of Agriculture. Agency jurisdiction issue is the area of the greatest variation among the six House bills. It also is very much tied to the issue of funding.

The Department of Agriculture clearly makes the most sense as the agency to be given responsibility for a Federal fish inspection program.

First of all, this is an issue of equity. The Department of Agriculture already has responsibility for the inspection of meat and poultry products—at a cost of $400 million annually, paid for directly by the Federal Government.

The fishing industry should not be subjected to a different agency, nor be required to pay for a comprehensive inspection system when its competitors—meat and poultry—are inspected under a federally funded system.

American consumers also must be able to look directly to a single Federal authority for confidence in the inspection of meat, poultry, or fish. They also must be confident that the first priority of the program is the public health interest—with inspections funded by public dollars, rather than the industry itself.

Second, this is an issue of effectiveness. The high range of estimates for a Federal fish inspection program is between $75 and $100 million annually.

In the United States, there are between 100,000 and 200,000 fishing vessels, and approximately 4,000 processing and wholesale vessels. The HACCP method will need to determine the exact scope of inspections, but the program definitely will occur on a large-scale.

Neither the Food and Drug Administration (FDA) or the National Marine Fisheries Service (NMFS) have the necessary scale to take on the assignment.

International trade is characteristic of the fishing industry. In the United States, 70 percent of fish products are imported, while 40 percent of domestic production is exported. The Department of Agriculture already has an overseas network of trade officials and inspectors. FDA has no comparable overseas capability; and the experience with the Department of Commerce has been that very low priority is given to fishing trade issues.

The investment for Federal fish inspection is significant.

If the program is to be effective, it must be undertaken by the agency that already has the size, the resources, the commitment, and the capability to make it work—and to sustain it over time.

The agency is the Department of Agriculture. Federal fish inspection is too big to give to an agency that is too small; too important to be lost among shifting priorities; and too critical to be relegated to any agency with insufficient funds.

The choice of the agency must be decided not on the basis of any Washington "turf battles," but rather, according to what best serves the public interest.

The CHAIRMAN. Mrs. Smith, along with Senator Mitchell I thank you. Please go ahead.

STATEMENT OF JO ANN SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE—Continued

Mrs. SMITH. My pleasure.

A FISH INSPECTION PROGRAM COULD BUILD ON USDA'S EXISTING MEAT AND POULTRY INSPECTION OPERATIONS

A fish inspection program could build on USDA's existing meat and poultry inspection operations. As you know, USDA's Food Safety and Inspection Service (FSIS) currently has a Federal inspection force in place at meat and poultry slaughtering and processing plants around the United States. These inspectors are present in every meat and poultry plant in the United States that prepares product for distribution in interstate or foreign commerce.

Currently, this field staff consists of approximately 7,000 inspectors and 1,200 veterinary medical officers. Each and every one of these employees is required to attend educational sessions at the FSIS training center located in College Station, Texas.

FSIS inspection personnel are backed up by a strong supervisory network consisting of five regional offices located around the country; 26 area offices; 189 inspection circuits; and, of course, the headquarters staff here in Washington, D.C. office.

TO COMPLEMENT THE FIELD WORK, FSIS ALSO HAS EXTENSIVE LABORATORY CAPABILITIES

To complement the field work, FSIS also has extensive laboratory capabilities. Three state-of-the-art in-house laboratories, 2 contract laboratories, and 315 accredited private laboratories all have extensive experience analyzing for chemical residues, microbiological contamination, processed product composition, and economic adulteration. Such laboratory facilities could be helpful in meeting the requirement under section 502(a) of S. 1245 of establishing "an inspection program designed to ensure the safety and wholesomeness of fish and fish products."

FSIS HAS A LONG AND SUCCESSFUL HISTORY OF EVALUATING THE MICROBIOLOGICAL AND CHEMICAL SAFETY OF MEAT AND POULTRY THAT COULD BE BENEFICIAL IN DEVELOPING A FISH INSPECTION PROGRAM

FSIS has a long and successful history of evaluating the microbiological and chemical safety of meat and poultry that could be beneficial in developing a fish inspection program. FSIS is committed to basing its regulatory decisions on scientific information. During fiscal year 1988, over 2.1 million analyses were completed on nearly 500,000 statistically selected samples.

PREVENTING RATHER THAN DETECTING PROBLEMS MUST ALSO BE RECOGNIZED

But the importance of a system for inspection designed with emphasis on *preventing* rather than detecting problems must also be recognized.

Seafood is very perishable, and delays in processing or processing under unsanitary conditions could markedly increase the potential for health-related problems. There is often not enough time to conduct laboratory analyses, and, where warranted, minimizing risks from perishability may require an in-plant program.

"RAPID TESTS"

Several "rapid tests" for meat and poultry have been developed by FSIS scientists and are conducted in the plant by an inspector, with the results being available almost immediately. In fiscal year 1988, over 1.2 million rapid test analyses were completed from approximately 250,000 samples. These rapid tests are used to determine such things as whether certain drugs or chemicals are present, if a product was canned or cooled properly, or if a different species has been used than is indicated on a label. Some of these types of tests could be developed for fish and seafood.

MANY OF THE PROVISIONS OF SECTION 502 ARE ACTIVITIES THAT FSIS HAS EXPERIENCED FROM MEAT AND POULTRY INSPECTION PROGRAMS AND COULD BE EXPANDED TO INCLUDE FISH AND SEAFOOD

Section 502 of S. 1245 established the proposed scope of a fish inspection program. Many of the provisions of section 502 are activities that FSIS has experienced from meat and poultry inspection programs and could be expanded to include fish and seafood.

For example, under section 502(b)(1), the inspection program is to "cover the processing, storage, and handling of meat from fish and fish products." One of the best ways to meet that requirement is by using the Hazard Analysis Critical Control Point, or the HACCP "systems" approach. FSIS has already incorporated HACCP procedures into certain aspects of our current processed food inspection operations, and is preparing for the implementation of HACCP-based inspection programs across-the-board.

It is widely agreed that the HACCP approach is the best for fish and seafood inspection as well, with the exception of molluscan shellfish. With HACCP, requirements focus on points in the slaughtering and food processing stage where food safety problems are most likely to occur—whether it is during manufacturing, while in storage, or at any point where the product is handled.

Another important element to be considered as part of a fish inspection program is found under section 502(b)(2), which requires that the inspection of imported and domestic fish products be on an equal basis. FSIS already has a strong import inspection program in place that could be modified to include seafood. We currently evaluate imported meat and poultry products to determine whether they comply with inspection and other requirements at least equal to those applicable to domestically prepared products.

DIFFERENT ASPECTS OF THE LEGISLATION

FSIS' International Programs staff reviews foreign inspection systems to ensure that they are at least equal to the programs required for U.S. producers under the Federal Meat and Poultry Products Inspection Acts. In addition, FSIS coordinates the inspection and certification of meat and poultry products for export abroad.

Section 502(b)(3) would provide for registering and inspecting facilities and vessels that process fish products. This provision is similar to FSIS' current application for inspection, blueprint approval and preoperational inspection programs.

Section 502(b)(4) requires the identification of "geographic areas producing fish and fish products that exceed the safety standards developed in accordance with this title." We understand that the intent of this section is certainly to recognize that many States already have fish inspection programs in place, and to work with those States to ensure there is no duplication.

We strongly believe that individual States should have a large role in the inspection of seafood, just as they do now in meat and poultry plants operating solely in intrastate commerce, and we have many States on a 50-50 funding basis for their State programs if their inspection programs are at least equal to Federal standards.

A labeling program similar to FSIS' could help reduce the confusion among consumers of fish and seafood as to exactly what they are purchasing, as well as to prevent fraudulent practices.

FSIS' compliance force could also be cross-utilized in a fish inspection program to meet the requirements under section 503 of S. 1245. A geographically dispersed compliance staff of approximately 130 compliance officers explains inspection and other requirements to industry officials, reviews records, and maintains a nationwide monitoring program of inspected products in commercial channels in order to prevent adulterated or misbranded meat and poultry products from reaching consumers.

The research and education activities—such as those authorized under section 504—would be important for any inspection program. There are many sources of risk to the consumer from fish and seafood—bacteria, viruses, natural toxins, parasites, chemical contaminants, decomposition, and mishandling.

The last four risks mentioned—chemical contaminants, decomposition, parasites, and mishandling—are all areas in which the current USDA meat and poultry inspection program has had considerable success in limiting any possible danger to consumer. These risk areas have been the focus of more frequent onsite inspection for meat and poultry.

Consumer education and outreach would be an important element of the fish and seafood inspection program. Currently, at FSIS we direct a very comprehensive public information and education program on issues such as food safety, food handling and labeling.

FSIS also staffs a meat and poultry "hotline" with trained home economists, who provide food safety information to callers. In fiscal year 1988, over 50,000 calls were received on subjects ranging from safe storage and preparation of foods to microbiological residues. The hotline staff already receives calls on fish and seafood from consumers, the media, et cetera, requesting information similar to that for meat and poultry.

Finally, under section 505, Interagency Cooperation would be essential to setting up a strong, workable fish inspection program. There is a great deal of expertise about fish inspection within other Federal and State agencies. All of that expertise and cooperation would be needed, and USDA would have no hesitation in asking for it.

Mr. Chairman, this concludes my testimony, and I will be pleased to answer any questions that you may have.

[The prepared statement of Mrs. Smith appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you. In the 20 minutes remaining for this panel, I would like Commissioner Young and Counsel Brennan to divide up the 20 minutes between the two of them. Then we can ask questions of all three of you so that we will leave time for the second panel.

So, Commissioner, if you would like to go ahead.

STATEMENT OF FRANK E. YOUNG, COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. YOUNG. Thank you, Mr. Chairman. I welcome the opportunity to be with you today and to discuss some of the very important health issues facing this Nation.

IS THERE A PUBLIC HEALTH PROBLEM ASSOCIATED WITH SEAFOOD?

My comments will be directed to the first step of the process: is there a public health problem associated with seafood? The data that I will present to you on some slides will show that the problem has been greatly inflated, I believe, and what I would also like to demonstrate is that we have a number of real problems just within a few miles of here—concern of drug abuse, of AIDS, of sexually transmitted diseases—and I know right now that the Senate and House are both working vigorously to try to find the appropriate resources that are required to meet the many demands of the Nation that already existed, yet also the two recent tragedies of the earthquake in California and the hurricane that struck the Southeast.

And thus I would plead with you, sir——

The CHAIRMAN. The drug czar has already come to the Judiciary Committee, on which I serve, about 6 months ago and said he was about to take care of the problem in the District of Columbia. So we apparently do not have to worry about that part anymore. I hope the disaster relief and AIDS relief will be a lot more effective than the cleanup of the District of Columbia has been. I would hope that we could match at least 1/100 of the rhetoric.

This is not directed at you, Commissioner. I will take it on my time. But I have heard a lot of talk about all the things we are going to do about drugs, AIDS, and disaster relief. I say disaster relief, the mayor of one city in the Carolinas had the temerity to suggest that because people were out in the rain 2 days later, homeless and nothing happened, the mayor suggested it was not working well. So he was not allowed to come along with the official party that came down from Washington. And I said the drug czar had a great press conference about how he was going to clean things up and stop the murders and the drug program in the District of Columbia. It is going to be great news to the residents of this city when it happens because they have not seen it.

And so I would hope that in some of these other things we might get somewhere, but please do not let me interrupt. [Laughter.]

RHETORIC MAY CAUSE A DIVERSION OF FUNDS WHICH MIGHT BE BETTER USED ELSEWHERE

Dr. YOUNG. Well, I am delighted that you did interrupt, sir, because you made my point. My point is that those are real problems. Those problems have been dealt with in our Nation's life with difficulty at best, and at times, rhetoric, as you pointed out. I believe that there has also been rhetoric in the seafood program, and what I would like to show you is that that rhetoric may cause a diversion of funds which might be better used elsewhere.

I would like, with that in mind, sir, to use these charts to demonstrate my points. First, in regards to the total number of foodborne illnesses, if one looks at outbreaks and compares these outbreaks to the total number of cases, one sees that 20 percent of the outbreaks and approximately 5 percent of the cases come from seafood, which is not a substantial problem [chart A].

If one looks at the number of cases per billion pounds and removes from the total seafood figures, the shellfish numbers, you will see we have roughly an even playing field [chart B]. Regretfully with the number of already mandatory inspections that occur in agriculture——

The CHAIRMAN. Would the number be that much different if raw shellfish was back in there?

Dr. YOUNG. Yes, it would. I do not have that. It would show it at about here, approximately 170. It is important to point out that in total number of cases, there are 1.7 million cases per year of chicken-borne illness compared to approximately 64,000 cases of illness per year associated with seafood. Of those 64,000——

The CHAIRMAN. Including the raw shellfish.

Dr. YOUNG [continuing]. 60,000 are related to shellfish and 4,000 are related to finfish. Therefore, a mandatory program designed to inspect seafood on a continuous basis is, in my opinion, as a physician questionable when we already see that programs that are mandatory with seals of approval still have a large number of diseases associated with them.

ONE HAS TO DISTINGUISH BETWEEN OUTBREAKS AND CASES

If one looks further at this, one has to distinguish between outbreaks and cases. And I will try to do this because the data that I showed you there referred to cases and there has been confusion between outbreaks, cases and risk assessment. If one looks at outbreaks you can see outbreaks contain multiple sizes of individual cases [chart C]. For example, an outbreak is two or more cases. That is fundamentally the way it is counted. Therefore, my submission to you, sir, is that as this committee functions, it should focus on total number of cases, not outbreaks, because people get sick.

If one carries this further now, and looks at some of the ways in which we deal with these figures, you see that in the year that I have selected here, 1987 [chart D], and I can give you a number of years, you will see that there were 37 outbreaks of seafood-borne illness and a total of 145 cases, 4 illnesses per outbreak; in contrast, with chicken that year, there were 8 outbreaks—a lower number of outbreaks—45 illnesses per outbreak, equaling 358 illnesses.

I remind you that as this is expressed, we remember that the total number—this chart shows cases in this particular outbreak—and these are the illnesses in this outbreak only—the total number of illnesses per year are 1.7 million per chicken as compared to 64,000 illnesses per year for fish. If one looks at seafood then one may summarize that there were 8,000 in this particular average period of time—8,147 illnesses, 755 outbreaks—which totals 5 percent of the illnesses or 20 percent of the outbreaks [chart E]. It is imperative as we look at public health figures to distinguish between outbreaks and illnesses. That has not always been done with great precision.

QUESTION OF PERCEPTION

Now there is a question of perception. It is important to look at the facts of what has occurred as we have increased our seafood consumption in the United States. From 1973-1987, seafood consumption has increased from 12 to 14.5 pounds per individual per year [chart F]. The illnesses over that period of time have stayed essentially constant. If one then plots the number of illnesses per pounds of fish consumed, the situation is getting better, not worse. I think that is a very important point when we look at any type of legislation. I would only say that this is a complicated issue.

SHELLFISH PROGRAMS

When we deal with the shellfish programs, the programs have multiple components [chart G]: general administration, laboratory procedures, growing area analysis, control of harvesting, controlled relaying, plant processing, depuration, and biotoxin studies.

As the program has been designed, it has been a voluntary Federal-State program. It has worked with the oversight of the Food and Drug Administration, and if we look at the results of these particular programs, in 1987 there were a number of States which did have nonconformities [chart H]. As you can see, they are listed here by name.

In 1988 with our more recent data, all but one of these have come into compliance [chart I]. I am sorry. This is in 1988. This was the problem of nonconformities. And by 1989 all but one of these States has reached compliance. It is none of the States represented by any of the individuals on this committee, sir.

PUBLIC HEALTH IS THE MOST IMPORTANT ISSUE ON FOOD SAFETY

With this in mind, I would just summarize by saying that public health is the most important issue on food safety. I believe that as we have looked at this, the data prepared by the Centers for Disease Control, which I have presented—I have a summary slide, if I could, even year by year [chart J]. I should state I presented this one before, and an ordinate was mixed up, but if you look year by year and you look at the number of cases, you will see an overall variability in the number of cases and the amount consumed. But the lines, as I showed you, were essentially as we saw before, and I can brief your committee at any time on a year-by-year analysis.

The **Chairman**. The chart, though, it is very similar to the one that the official who briefs us in defense appropriations on Star

Wars uses. I think you get them from the same source. I am sorry. A little humor there. Go ahead. Very little.

Dr. Young. I apologize. I do not think we have ballistic clams coming from the State of Maine at this time, to the best of my knowledge, sir.

The Chairman. Probably it would be as effective as Star Wars.

Dr. Young. Well, they both need a safety net.

The Chairman. There you go. [Laughter.]

The Chairman. I will leave it alone.

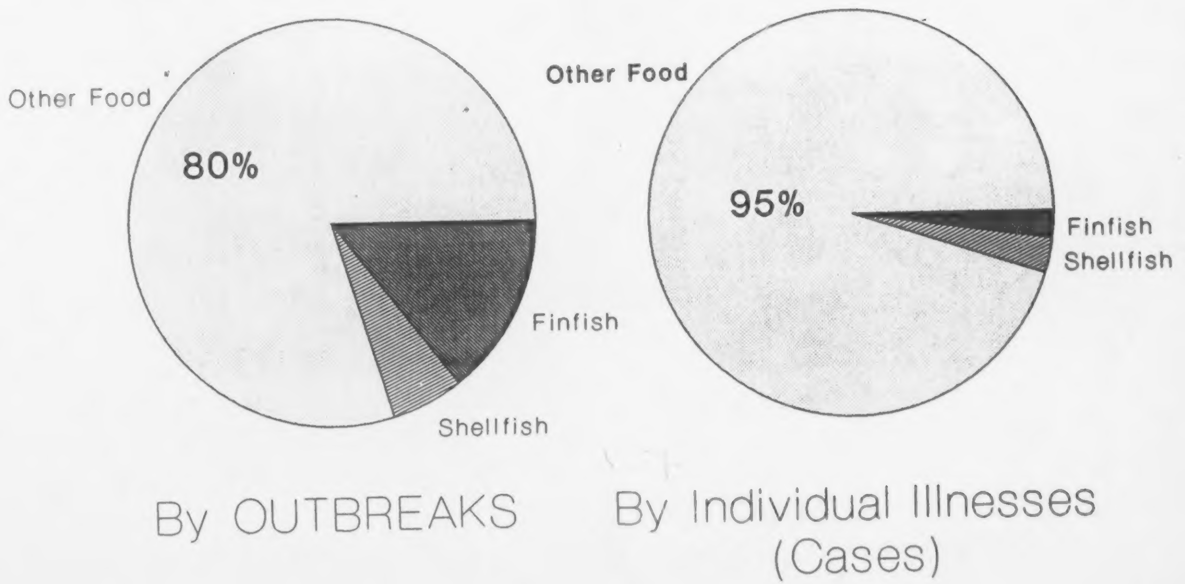
FISH AND SHELLFISH AND ILLNESSES CONSUMED PER POUND

Dr. Young. If one looks in summary at the amount of fish and shellfish and illnesses consumed per pound, I think the data shows unequivocally that there is not an increase in shellfish and finfish illness, but in fact a decrease compared to a mandatory program that inspects each and every chicken. Seven million illnesses per year associated with chicken compared to 64,000 illnesses per year associated with shellfish and fish is in stark contrast. We do not believe at this time that there is a major public health problem. Not that we do not need to increase inspection. I have been on record for that for a period of time. Not that we do not need to increase inspection. I have been on record for that for a period of time. Not that we do not already have a portion of this as mandatory inspection, but I would like to submit that a lot of emphasis needs to be given to these particular figures. And with that, Mr. Chairman, I would be happy to answer any questions that I could.

[The charts referred to by Dr. Young follow:]

CHART A

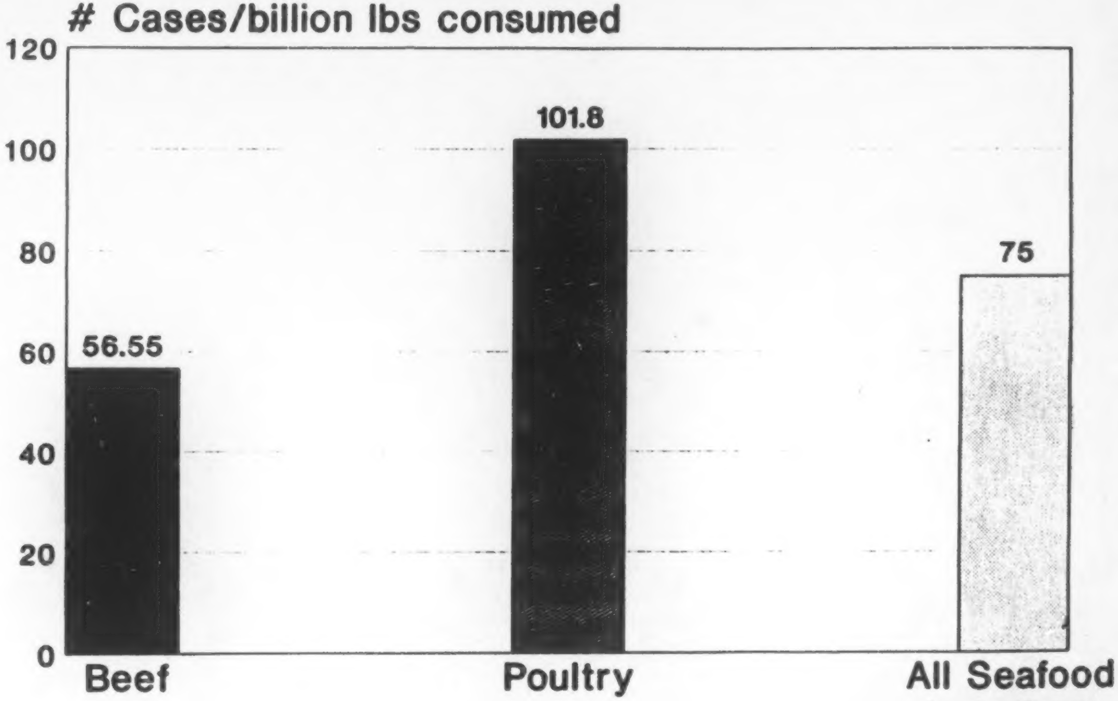
Comparing Foodborne Disease Data
Outbreaks vs Individual Illnesses



CDC Surveillance, 1973-1987

CHART B

Number of Cases per Billion Pounds Consumed (1973-1987)



CDC Surveillance Data & ERS, USDA Consumption Data

CHART C

Outbreak: Two or more cases of illness linked to a common food source

WHICH HAS THE GREATEST PUBLIC HEALTH IMPACT???

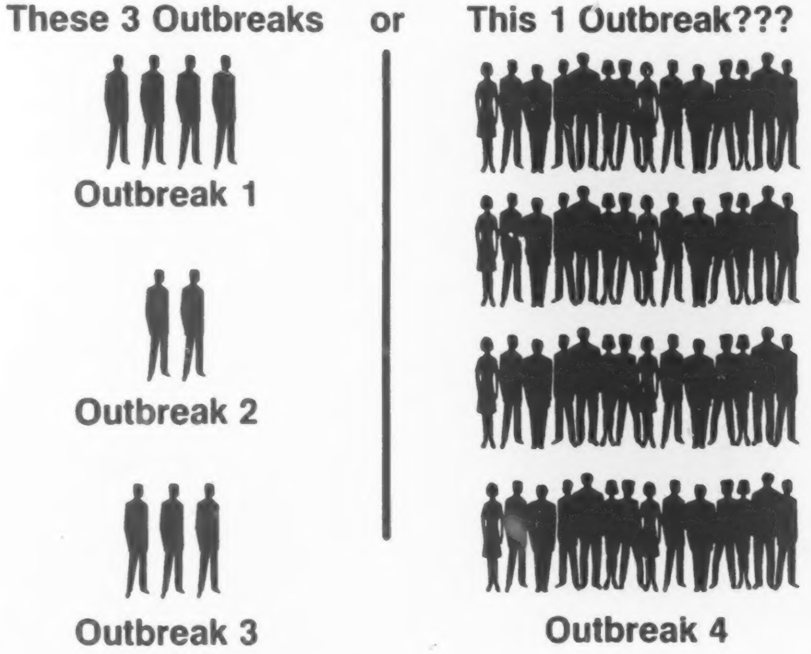
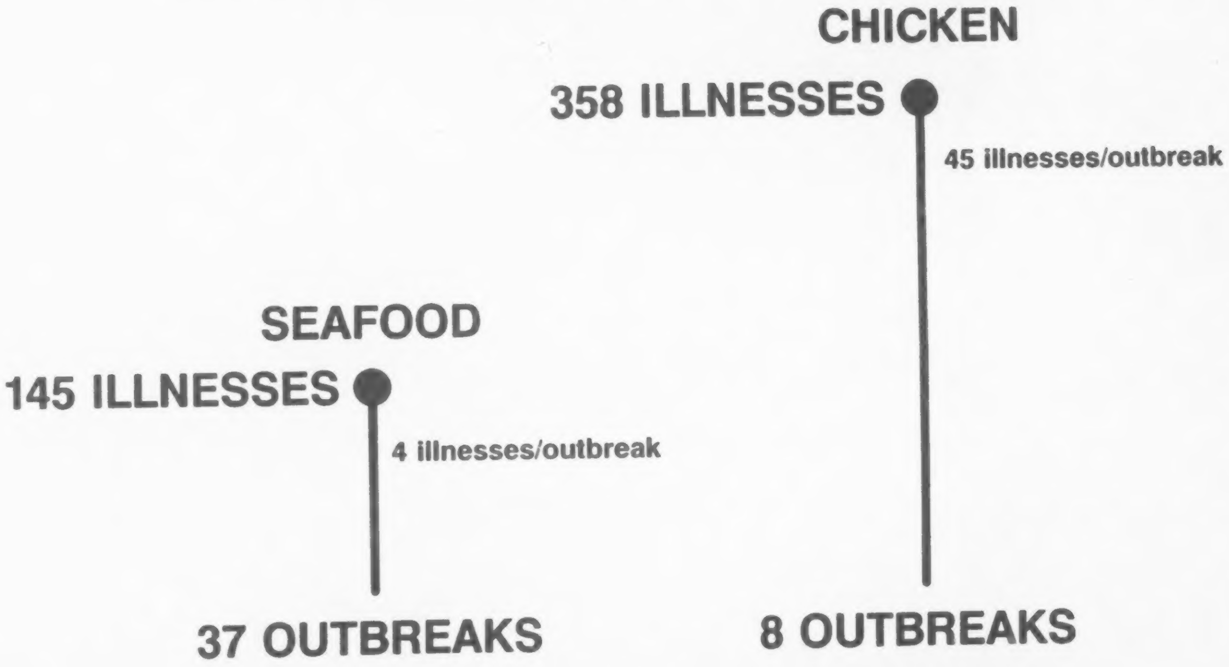

These 3 Outbreaks
or
This 1 Outbreak???
Outbreak 1
Outbreak 2
Outbreak 3
Outbreak 4

CHART D

1987 Illnesses vs. Outbreaks**



** These are reported illnesses and outbreaks only

CHART E

Seafood

Illnesses vs. Outbreaks - 1973-87

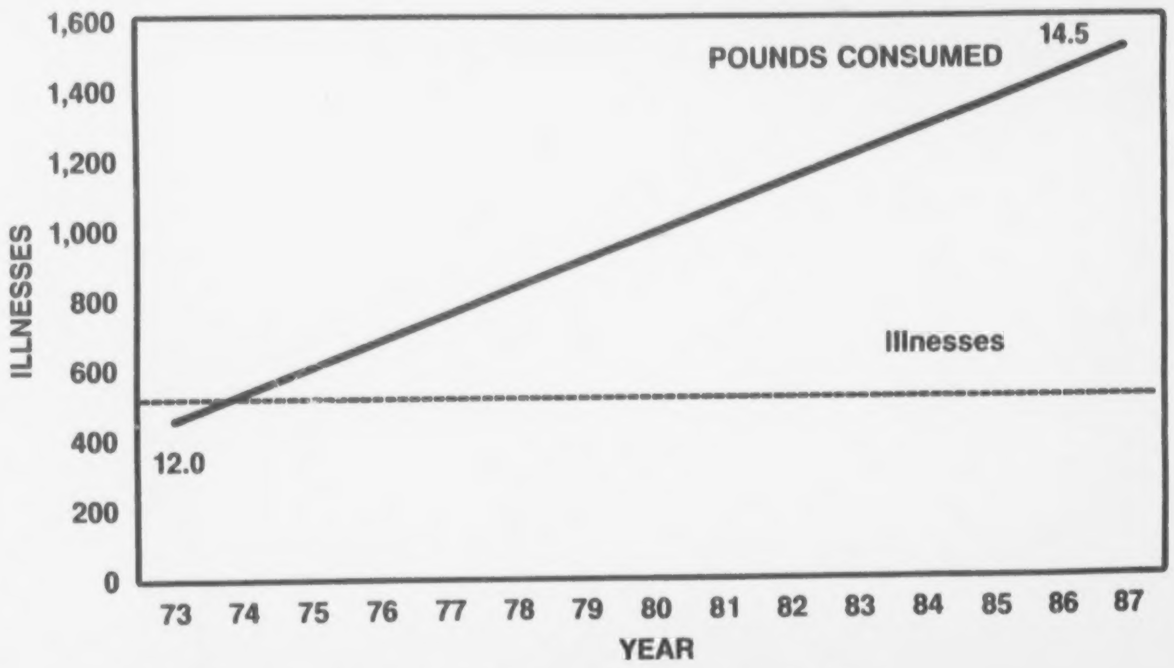
8,147 Illnesses ↕ **755 Outbreaks**

=

5% of Total Illnesses ↕ **20.4% of Total Outbreaks**

CHART F

Fish And Shellfish
Trends In Illnesses And Per Capita Consumption 1973-1987



CDC Surveillance Data & ERS, USDA Consumption Data

CHART G

FDA Evaluation of State Shellfish Sanitation Programs

Program Components:

1. General Administrative Procedures
2. Laboratory Procedures
3. Growing Area Survey and Classification
4. Control of Harvesting
5. Controlled Relaying
6. Plant Processing and Shipping
7. Depuration
8. Biotoxin - Paralytic Shellfish Poison (PSP)

CHART H

Summary of Major Nonconformities with NSSP Criteria
1987
(October 1, 1987)

Connecticut	New	Growing Area
New Jersey	New	Depuration
Massachusetts	New	Growing Area & Depuration
Oregon	Repeat	Admin, Growing Area & PSP
California	Repeat	Growing Area & PSP
Louisiana	Repeat	Patrol
New York	Repeat	Growing Area
Texas	Repeat	Growing Area
Maine	Repeat	Growing Area

CHART I

Summary of Major Nonconformities with NSSP Criteria
1988
(October 1, 1988)

Delaware	New	Growing Area
Maryland	New	Plants
Mississippi	New	Growing Area
Florida	New	Patrol
Oregon	Repeat	Admin, Growing Area & PSP
California	Repeat	Growing Area & PSP
Louisiana	Repeat	Patrol
New York	Repeat	Growing Area
Maine	Repeat	Growing Area
Connecticut	Repeat	Growing Area & Patrol
Massachusetts	Repeat	Growing Area & Depuration

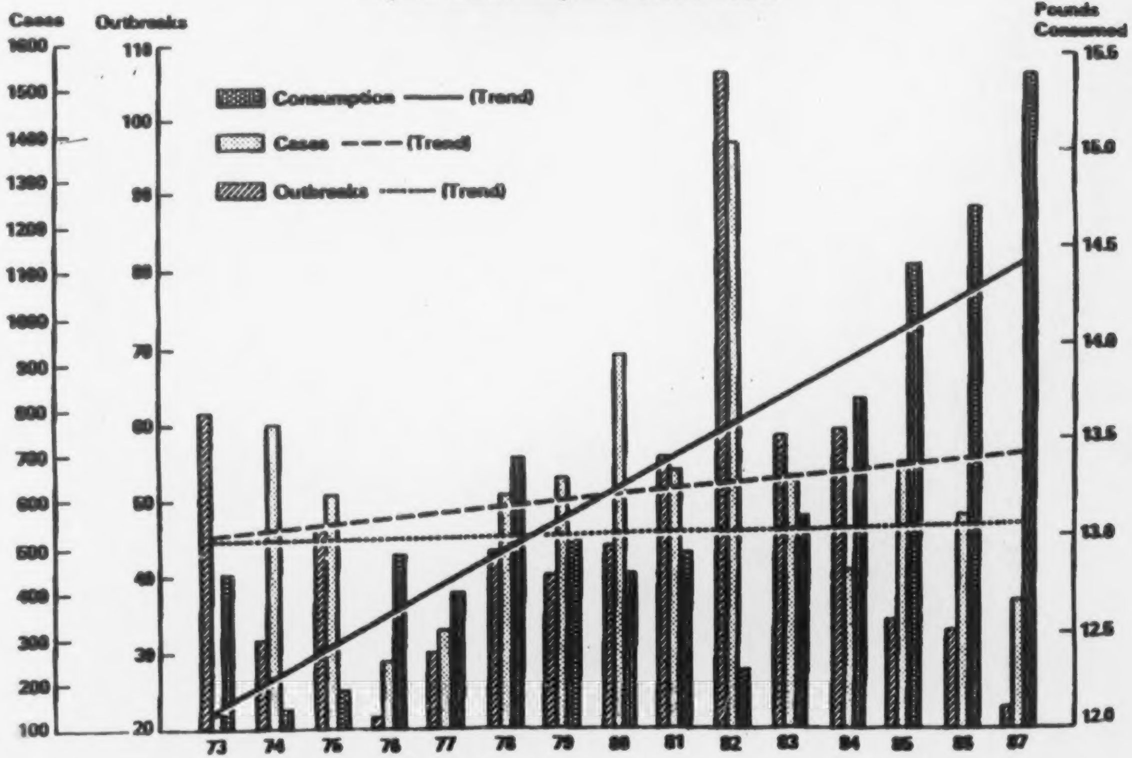
Progress:

As of October 1, 1989 only one still has significant problems.

CHART J

Fish and Shellfish

Trends in Cases and Outbreaks Compared to Trend in per capita Consumption (1973-1987)



CDC Surveillance Data & ERS, USDA Consumption Data

[The prepared statement of Dr. Young appears at the conclusion of the hearing.]

The **Chairman**. Thank you, Commissioner.

Mr. Brennan.

STATEMENT OF JAMES W. BRENNAN, DEPUTY GENERAL COUNSEL, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE, WASHINGTON, DC, ACCOMPANIED BY THOMAS BILLY, DIRECTOR, TRADE AND INDUSTRY SERVICES, OFFICE OF THE NATIONAL MARINE FISHERIES SERVICE

Mr. **Brennan**. Thank you, Mr. Chairman. I am accompanied today by Mr. Thomas Billy, who is the Director of our Trade and Industry Services, Office of the National Marine Fisheries Service.

I WANT TO SHARE WITH YOU ONE OF THE ALTERNATIVES FOR AN ENHANCED SEAFOOD INSPECTION PROGRAM THAT IS NOW BEING CONSIDERED WITHIN THE ADMINISTRATION

I want to share with you one of the alternatives for an enhanced seafood inspection program that is now being considered within the administration. And it is, parenthetically, one that we in the Department of Commerce favor. In developing our proposal, we have taken into account the unique nature of the fishing industry. Fish is hunted and harvested from many areas by many, many harvesters. Over 100,000 vessels are actively engaged in fishing.

We are talking about 500 different species of edible fish, 100 of which are important commercial species in the United States. In building our proposal, we have looked to NOAA's fisheries' expertise and our long history of involvement in regulating at-sea fishing activity, inspecting fish and fish products at points after harvest, through the marketplace and our applied research into the utilization of fishery products.

WE CONTINUE TO BELIEVE THAT THE KEY IS TO MAINTAIN A CONTINUING ROLE FOR FDA AND NOAA IN SEAFOOD INSPECTION

We have carried out these activities in collaboration with the Food and Drug Administration, and we continue to believe that the key is to maintain a continuing role for FDA and NOAA in seafood inspection. In our proposal, we foresee strengthening our relationship with the Food and Drug Administration and bringing in the States as full partners in providing consumers with assurances of safety and quality of seafood. And as Commissioner Young has suggested, we are dealing here with a question largely of perception on the part of consumers.

KEY ELEMENTS THAT NEED TO BE ADDRESSED IN DECIDING HOW TO IMPLEMENT A NEW SEAFOOD INSPECTION PROGRAM

We believe that there are certain key elements that need to be addressed in deciding how to implement a new seafood inspection program, and I would like to address four of them.

POTENTIAL CHANGES IN SEAFOOD INSPECTION PHILOSOPHY AND PROGRAM DESIGNS

First, the potential changes in seafood inspection philosophy and program design that will be necessary. Seafood inspection must be based on problem prevention backed by strong enforcement. This approach has been adopted by leading seafood producing countries such as Canada. Such a system would include developing and implementing a seafood inspection program based upon the Hazard Analysis Critical Control Point principles, the so-called HACCP principles, tailored to the needs of the specific fishery.

This program must address issues of plant and vessel sanitation, product safety and economic fraud. There must be expanded monitoring of fishery products for both chemical and microbiological contaminants. There must be prohibitions or restrictions through fishery management plans on the harvesting of fish from certain areas to prevent processing and marketing of unsafe fishery products.

We believe that there must be developed and adopted minimum sanitation standards for harvesting, processing, transporting and storage of fishery products and the developing or amending of fishery product trade standards which would be consistent with international requirements for quantity, minimum quality, packaging and labeling.

ADEQUACY OF PRESENT REGULATORY AND ENFORCEMENT AUTHORITIES

Second, there are also needed changes in regulatory and enforcement authorities. We believe that we must create a new mandatory plant and vessel registration and certification system. There must be a process for granting access to records pertinent to HACCP principles. There must be a provision for granting product detention authority to inspectors for domestic products. We must impose stricter civil and criminal penalties for specified violations and prohibited acts. And we must establish and monitor technical arrangements with appropriate agencies of foreign countries for mutual acceptance of inspection systems or analytical results.

APPROPRIATE FEDERAL/STATE RESPONSIBILITIES

Third, I think we should address the Federal-State relationship. I think it is critical that there be a continuation of the joint responsibility of NOAA and FDA for seafood inspection and enforcement with NOAA as the Federal agency for day-to-day inspections with oversight by the Food and Drug Administration.

We must maintain current responsibility within FDA for health standards and have FDA oversee NOAA fisheries inspections and enforcement activities, with particular emphasis on public health issues. There must be—this is a very important feature—full cooperation on a partnership basis with those States and foreign countries that have in place a program fully equivalent to Federal requirements.

PROGRAM COSTS/FUNDING

Fourth, the question of program costs and funding has been alluded to earlier. In our view, it is appropriate that funding for any increased Federal seafood inspection activities be paid for by the industry through user fees.

THE APPROACH THAT I HAVE OUTLINED

The approach that I have outlined, briefly, would continue the Food and Drug Administration's present role of risk assessment and establishing tolerances, where appropriate, with respect to seafood product safety, but in closer cooperation with the Secretary of Commerce.

At the same time, NOAA would assume the Federal role for day-to-day inspections under the oversight of the Food and Drug Administration. We believe that legislative changes in seafood inspection authority should address problems of sanitation, product safety and economic fraud at all levels of seafood product and distribution. Our approach therefore mandates coverage from the growing waters to the marketplace. It is much more effective and cost efficient to deal with problems related to seafood at sea before violative material is processed and enters distribution channels.

We believe any regulation of harvest areas for public health purposes should be carried out under existing NOAA fishery management authority. Under the Magnuson Act, Mr. Chairman, we routinely open and close harvest areas tied to conservation and management objectives. Most recently, NOAA took emergency action under the Federal Surf Clam Fishery Management Plan to prohibit harvests of surf clams in an area of Georges Bank off New England. This action was taken because of levels of paralytic shellfish poisoning in surf clams that had exceeded recognized safety standards. As I stated, authority to regulate at sea, to address product safety and vessel sanitation concerns, is needed and should be carried out in concert with current fisheries management activities.

To implement a comprehensive mandatory inspection program, I believe a full partnership with the States will be required. Currently, the States are providing varying degrees of inspection coverage in the seafood area.

Authority is needed to delegate inspection activities to States with programs meeting Federal standards. We must build on the partnership with all the States, supplementing them with Federal grants covering a portion of the costs for States with programs approved by the Food and Drug Administration and NOAA.

By building upon existing State infrastructures, we can minimize the need for potentially redundant Federal bureaucracies where State programs can demonstrate their ability to apply Federal standards. If a State cannot, or chooses not to, administer Federal standards, then of course, a direct Federal presence would be required.

To summarize, to assure public confidence in the quality and safety of seafood we must develop an effective program addressing growing waters, plant and vessel sanitation, harvesting and processing at sea, product standards, exports, imports and consumer education. And we believe that the best way to deliver that system is to build upon the existing expertise and resources of NOAA, the Food and Drug Administration and the States acting in partnership. Thank you, Mr. Chairman.

[The prepared statement of Mr. Brennan appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you.

You were saying that NOAA has had kind of direct contact with the harvesting end of the seafood industry. Now we are not suggesting an inspector on every one person boat every day. But when we think of these large processing ships. I would assume they would need inspection on a nearly continuous basis. Is that correct?

Mr. BRENNAN. Mr. Chairman, I think you are getting at the point that really is at the heart and essence of the HACCP principle. What you would do when you are looking at at-sea processing, you would develop with industry and analyze the critical control points that need to be under control in order to assure that the product coming off that vessel, that processing vessel, is indeed safe and wholesome.

The CHAIRMAN. How would you ensure that? Would you have continuous inspection?

Mr. BRENNAN. No, sir, what we would propose to do would be to have the processor keep records of his process to show that the process is, in fact, under control. That there would be periodic visitations by an inspector who would look not only to see that the plant, the vessel was clean and process appeared to be going on in compliance with the standards and regulations, but he would also look at the production records to make sure that at each critical control point in the process, is, in fact, under control.

The CHAIRMAN. There would be nobody there in between these inspections? Nobody there in between these visits? All you would have to go on would be the record kept by the ship?

Mr. BRENNAN. That is generally true. If looking at the product coming off that ship indicated that there was a problem, then, of course, there would have to be increased surveillance. The point is that with respect to a processing vessel, the at-sea time may be somewhat prolonged just because of the logistics of getting an inspector on and off. He may be there for several days. But it would not be our feeling that it would be necessary in order to assure the consumer that the product is being appropriately treated that there be an inspector onboard all the time.

The CHAIRMAN. And Commissioner Young, am I correct in saying that it is the FDA's position that we do not need a seafood inspection program beyond anything that we already have?

Dr. YOUNG. Mr. Chairman, I did not focus on the issue of the program per se. My official comment would be this: that we are actively looking to determine what increases would be relevant. There are some things that the Food and Drug Administration feels should be increased, particularly periodic inspections, as was defined by Mr. Brennan, so that there would be more inspection of some of the gathering vessels. We also think that every part of the chain has to be examined. But we do not believe——

The CHAIRMAN. But you do not see anything necessary as envisioned by this legislation?

Dr. Young. We do not believe that a continuous inspection program would necessarily provide the type of safety that would be required, particularly in view of the public health figures that I pointed out. The major focus——

The Chairman. This calls for mandatory inspection, not a continuous inspection. Don't you see the need for this kind of mandatory inspection that we call for in the bill?

Dr. Young. There is already a mandatory inspection program. The factories are under mandatory inspection by the Food and Drug Administration. I do not quarrel with the concept of mandatory versus voluntary. I think that discussion needs to be taken under great consideration. We do feel that a partnership has worked well. The voluntary program has worked, but I think an increase of——

The Chairman. We are talking about the 85, 90 percent that do not have inspection. The bill calls for mandatory inspection. Does FDA favor that or not?

Dr. Young. FDA would favor, on balance, a mandatory inspection program but not at 100 percent level.

The Chairman. Now Secretary Smith, I want to make sure I understand. You have how many food inspectors at USDA approximately?

Mrs. Smith. I will let Dr. Crawford give you the specifics.

Dr. Crawford. Mr. Chairman, we have approximately 10,000 employees in the Food Safety and Inspection Service. Of that number, 75 percent are actually inspectors.

The Chairman. About 7,500 inspectors in there?

Dr. Crawford. Yes, sir.

The Chairman. In how many plants?

Dr. Crawford. They are in combined processing and slaughter plants, they are in about 7,000 total plants.

The Chairman. And Commissioner Young, including medical personnel, how many inspectors does FDA have?

Dr. Young. The budget for FDA provides for 900 inspectors.

The Chairman. How many do you have?

Dr. Young. 900 inspectors.

The Chairman. You do have 900?

Dr. Young. Yes, we do. And that covers the entire economy of $570 billion, and for the Fish Inspection Program, we have approximately 100 inspectors. The bulk of those are focused on the factories dealing with mandatory inspection of processed seafood.

The Chairman. Are the bulk of your inspectors in the field or——

Dr. Young. All of our inspectors are in the field.

The Chairman. So 100 percent of your 900 inspectors are in the field?

Dr. Young. That is correct, to the best of my knowledge.

The Chairman. And at USDA what percentage of your inspection personnel are in the field?

Dr. Crawford. We have about 90 percent of our inspection personnel in the field, and we have, of our total personnel, about 90 percent in the field and about 10 percent in headquarters. We have about 800 people here and about 9,000 in the field so we have an exact flip-flop.

The **Chairman**. Commissioner Young, you do not have any back in headquarters?

Dr. **Young**. Mr. Chairman, I would define those inspectors that are active as those that are in the field inspecting; those people in headquarters are overseeing the program. They would already be included in about a 10 percent overhead, but they are not what we count as active inspectors.

The **Chairman**. You may have some problem with that terminology when you get back home, but that reminds me of the big mistake made years ago when I was a law student here in Washington. And one of their terrible D.C. snowstorms. I think there was at least 2 to 3 inches of snow. Some of us think of this as a kind of an early September dusting back home. But they announced that all nonessential Government personnel stay home. There was a terrible traffic jam because nobody wanted to be considered nonessential so everybody came to work. So when your nonactive inspectors chat with you when you get back, make sure you get the full definition. We will leave the record open long enough to get a definition to keep you from being hanged when you get back there.

Dr. **Young**. Mr. Chairman, I appreciate your kind consideration, particularly as you raise snow as an analogy. I am from Rochester, New York, and we measure it in feet rather than a light dusting. But to the best of my knowledge, we count our inspectors as those that are in the field.

The **Chairman**. I see.

Dr. **Young**. We do have headquarters' enforcement programs, but these personnel are not actively inspecting firms.

The **Chairman**. Thank you.

USDA and FDA operate import programs. The United States imports about 60 percent of its consumed seafood, if I am correct. How does USDA's import product inspection program work?

Dr. **Crawford**. We do a couple of things, Mr. Chairman. One is for a product to be exported from the United States, we inspect that in our usual domestic program and then we provide backup check sampling at the border before it leaves this country. For those countries that wish to export to the United States, we inspect first the country and their programs to be sure they are eligible to export and meet an "equal-to" criterion. At the present time, there are 40 countries eligible to export, and of those 40 countries, about three-fourths have plants that have actually been approved.

So we inspect them, Mr. Chairman, onsite. Not only that, we maintain in most of the embassies of the United States abroad an agricultural attaché, and in some of those a veterinary attaché, to assist with the inspection programs. And this was particularly effective, as perhaps you know, during the Chernobyl crisis.

The **Chairman**. I recall that well. I have a number of other questions, but in the interest of time I will hold them for the record and yield to Senator Gorton.

Senator **Gorton**. Commissioner Young, when you say you are in favor of a mandatory inspection program, but not at 100 percent, what do you mean by that? What does mandated mean? How would you make the selection of what to inspect?

Dr. **Young**. I think the Government needs to have in the leadership role in the analysis by looking at critical control points and assuring that each particular inspection activity fits the particular species of fish. We also feel that a large amount of protection can occur by the appropriate processing and handling of the fish.

We would focus our maximum attention (because of the public health interest) on shellfish per se. We do not believe that merely inspecting shellfish visually will find the problems. You will not see hepatitis virus by looking at a shucked oyster. You will not see toxins by examining a fish. Pesticides will not be seen that way. And in perspective, I think we have to consider that the cost of the entire USDA inspection program for just meat and poultry is equal to the amount of resources that are provided to the whole Food and Drug Administration for looking at blood, drugs, devices, et cetera, as well as food inspection.

We have, over time, not gone through our congressional mandate to require a mandatory, continuous, inspection of anything. I hope it does not shock you, but blood banks are inspected only once a year. We do not have an FDA inspector in each and every blood bank looking at each and every unit of blood. The same is true in the manufacture of devices. Yet the U.S. Congress and administration in its wisdom have seen fit to look at each and every bird. The same is true with looking at drugs.

You eat your medicinal drugs raw. You cook your chicken. By and large cooking will take care of the salmonella in children, but if there is a problem with that medicine, it will not be solved by merely examining it. Similarly, regretfully, if you were to have a pacemaker, not only do you put it in raw, but once implanted, unlike the drug, you do not survive if it is implanted wrong, and that pacemaker may be in you forever. Yet we do not have a mandatory inspection of each and every pacemaker and each and every pacemaker plant 100 percent of the time.

I think those same principles of relying on critical control point analysis of various hazards can be applied to the seafood industry as well. In looking at the programs that we have to deal with with AIDS, drug abuse and others, in my professional opinion as a physician, it would be a wanton waste of dollars to look at each and every product. But that does not mean that we do not have a mandatory program.

A mandatory program does not mean 100 percent continuous inspection. So therefore with no contradiction I can say that I favor a government-led, mandatory program that would be in partnership between the Federal Government and the States, that would focus on the identification of critical points and design a program in relation to the hazards that are associated therewith. With that in mind, we would focus primarily on shellfish. As I said, 60,000 out of the 64,000 cases come from that product, not because it is inherently an unsafe product, but we consume that product raw, intestinal tract and all, unlike chicken or turkey.

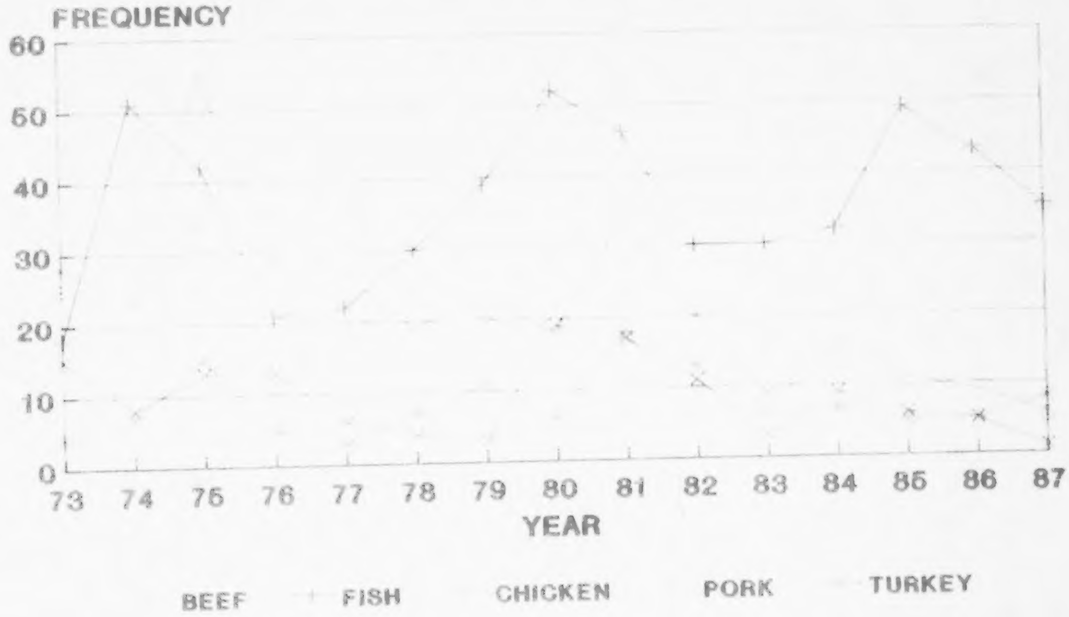
That results in increased exposure to risk. Cooking and processing reduces that exposure. Anytime we eat raw flesh of an animal we expose ourselves to risk, whether it be the hunter and tularemia, or whether it be eating raw chicken or beef or seafood. Those hazards should be addressed through our consumer education. We do not believe that a mandatory program of inspecting each and every fish is required, and I would submit it is a waste of money.

Senator **Gorton**. Mrs. Smith, would you like to comment on that question and that response?

Dr. **Crawford**. I would like to. I believe that in particular the figures that were presented with respect to the risk and so forth, we would like to submit some actual figures based on data from the Centers for Disease Control (CDC) rather than extrapolated figures, which we think will make the case for the kind of inspection that we do or are proposing to do along HACCP lines with processed products including meat and poultry.

[The material referred to by Dr. Crawford follows:]

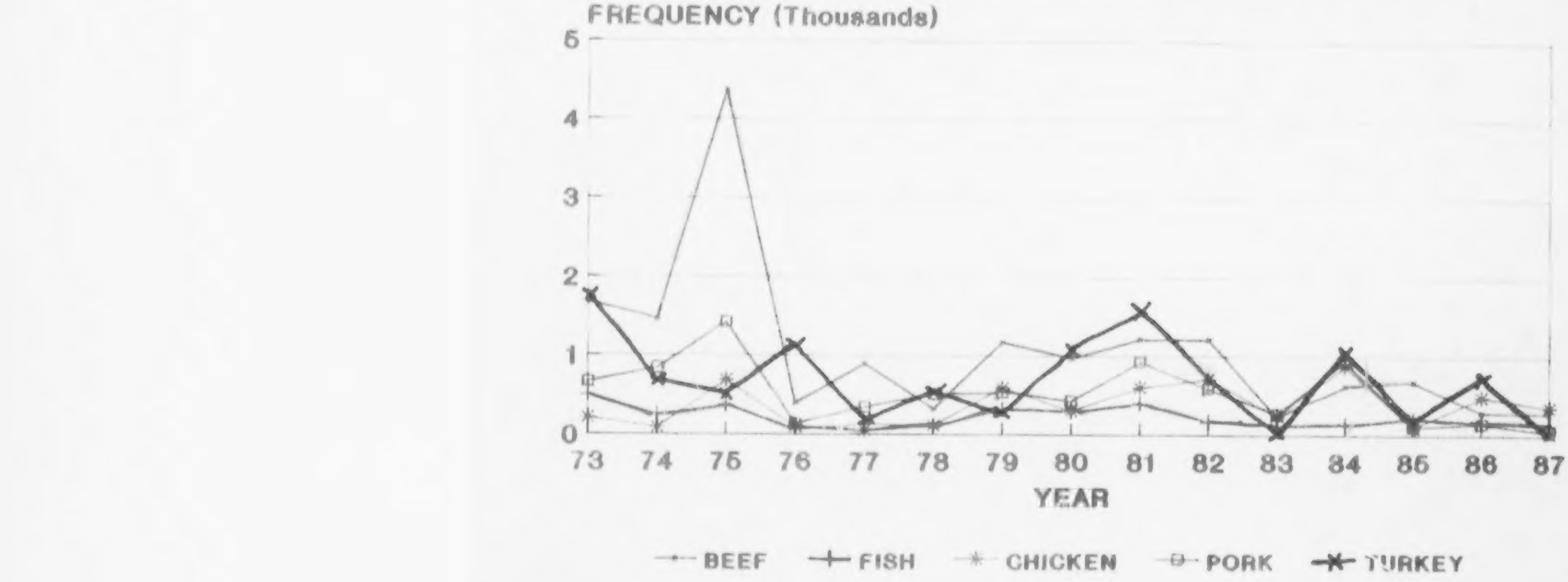
FOODBORNE ILLNESS OUTBREAKS FROM KNOWN VEHICLE GROUPS



FROM: CDC 11/1/89

FSIS,S&T,MD 11/8/89

FOODBORNE ILLNESS CASES FROM KNOWN VEHICLE GROUPS



FROM: CDC 11/1/89

FSIS,S&T,MD 11/8/89

FREQUENCY OF FOODBORNE CASES FROM KNOWN VEHICLE GROUPS

VEHICLE GROUP	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	TOTAL	%age of TOTAL
BEEF	1677	1463	4371	402	899	332	1171	974	1212	1212	226	627	677	291	278	15812	9.6
PORK	664	840	1420	136	347	513	540	431	925	592	268	941	109	150	48	7924	4.8
CHICKEN	208	88	687	98	52	117	590	303	602	711	252	873	102	487	358	5528	3.4
TURKEY	1740	685	507	1128	191	527	281	1086	1568	716	26	1039	186	711	28	10419	6.3
SHELLFISH	294	39	174	63	137	387	118	212	302	1371	630	623	133	156	9	4648	2.8
FINFISH	498	252	370	65	133	104	320	292	395	173	115	136	204	164	136	3357	2.0
EGGS	422	325	24	0	18	74	161	58	51	117	433	0	212	184	146	2225	1.4
DAIRY	37	223	112	718	114	270	117	275	1884	368	576	251	16904	108	32	21909	13.3
FRUITS & VEGS	88	94	23	64	106	156	63	183	367	57	2036	43	378	511	14	4183	2.5
UNKNOWN	3770	9142	6261	6506	4413	4832	5951	4446	3092	9615	6701	6459	7414	5214	4879	88690	53.9

Source: Centers for Disease Control, Nov. 1989

FREQUENCY OF FOODBORNE ILLNESS OUTBREAKS FROM KNOWN VEHICLE GROUPS

VEHICLE GROUP	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	TOTAL	%age of TOTAL
BEEF	28	23	55	29	27	19	23	18	34	20	9	16	11	9	6	327	8.8
PORK	25	31	34	11	18	25	21	13	17	10	8	14	9	11	5	252	6.8
CHICKEN	4	7	15	5	3	7	11	6	18	13	6	7	5	5	8	120	3.2
TURKEY	15	8	13	13	6	4	3	19	17	11	3	9	6	5	1	133	3.6
SHELLFISH	4	9	9	8	11	21	14	17	8	67	23	9	6	5	2	213	5.8
FINFISH	18	51	42	21	22	30	39	52	46	30	30	32	49	43	35	540	14.6
EGGS	2	1	3	0	2	2	5	1	2	4	3	0	3	4	6	38	1.0
DAIRY	4	6	11	8	4	7	3	7	13	9	17	6	10	3	3	111	3.0
FRUITS & VEGS	20	22	17	11	16	10	12	15	21	22	20	10	19	20	6	241	6.5
UNKNOWN	90	153	178	150	165	91	84	98	90	100	116	131	103	96	79	1724	46.6

Source: Centers for Disease Control, Nov. 1989

Dr. **Young**. But I think, Senator, the record would show the Department of Agriculture even itself asked for less than continuous inspection of meat and poultry, which was not granted, and which must have meant in some ways that they felt that a less than continuous inspection might be adequate. Knowing my good colleague, Dr. Crawford's integrity, he would not permit anything less.

Dr. **Crawford**. Let me also compliment you on your integrity. Is there anything else. I like your uniform also, Dr. Young.

Dr. **Young**. You can use doctor or admiral. It is your choice.

Dr. **Crawford**. Thank you, Dr. Young. [Laughter.]

Senator **Gorton**. Thank you. Senator Daschle, that is it.

Senator **Daschle** [presiding]. Senator Cochran.

STATEMENT OF HON. THAD COCHRAN, A U.S. SENATOR FROM MISSISSIPPI

Senator **Cochran**. Well, thank you very much, Mr. Chairman.

As members of the committee know, we have been working on this legislation for some time now, meeting with various people who are interested in this subject, including consumer groups as well as producers. In Mississippi, the fish industry is a very important economic activity. The domestic farm-raised catfish industry in Mississippi generates about $1.5 billion in economic activity each year. Over 80 percent of the freshwater catfish that is sold throughout the United States is grown and processed in the State of Mississippi.

We also have a very active and substantial Gulf coast seafood industry producing shrimp and oysters and other fish products. So our State is very interested in this legislation and for that reason I join with Senator Mitchell in introducing this bill, S. 1245, which is the subject of our hearing today.

And it is a very helpful exercise, I think, to get the benefit of the observations and comments of these experts who are here today at our committee. I want to thank you all for your attendance and for your helpful testimony. Your cooperation in our analysis of the legislation and some of the issues that are raised by it will be very helpful to us as we shape the final product and I hope report a bill to the Senate for action sometime soon.

In connection with some of the things that have been said, I wonder, and I am remembering some earlier hearings on similar subjects, how do we reconcile the Federal responsibility in this area with State responsibility? I would like to ask the Department of Agriculture about what we would do in the event we run into State seafood inspection programs that might conflict with, or be duplicative of, the Federal effort. Could I have your comments and your views on how we would deal with that problem, or is it a problem?

Dr. **Crawford**. Yes, Senator. As you know, we have now State-Federal cooperative programs with the majority of the States for the inspection of meat and poultry products. And we would propose to do this system the same way for fish products. Each year, under the law and by regulation, we audit each one of those programs.

Our Review and Evaluation Branch conducts an audit which is under the general supervision of our Office of Inspector General. We look at several things within those programs. One is accounting. The second is whether or not the program is being conducted consistent with national uniformity so that each State is doing the same level of inspection. Third, the audit enables us to determine if a program conforms with international standards.

Also the residue sampling and microbiological sampling has to be consistent from State to State. So it very much is a monitoring of the program, and if there are deficiencies, we have from time to time had to ask for corrections. We have also had to, in some cases, delist a State program because the deficiencies could not be corrected. We operate a 50-50 monetary sharing program. That is primarily what we looked at originally, but now we have audited, over the past number of years, every aspect of the program.

Senator COCHRAN. Dr. Young, I remember one day we had a hearing in the Labor Committee which has jurisdiction over certain aspects of food safety and the like. You may recall a comment that I made at that time. It is frustrating to see the public persuaded more by the testimony of a movie star at one of our hearings than by the testimony of a distinguished panel of experts such as the Commissioner of the Food and Drug Administration, and others, whose responsibility and whose lifetime of training has been in these areas.

What is the answer to that? If we develop a national food safety inspection program for seafood and everything, how are we going to convince the American people that they should have confidence in it?

Dr. YOUNG. I think that is probably, Senator Cochran, one of the most difficult issues that we have to face. I have not served in government nearly as long as you gentlemen at the table, but I have been impressed in the few years that I have served that we make some of our own problems ourselves. By not putting into context the total magnitude of the program, we end up scaring individuals.

I think the chairman in his opening statement of the hearing said our food supply is among the very safest in the world, and I agree. But if we focus on each tree that may have some disease in this forest and blow it out of perspective, then we see coming back at us a public outcry that our food is not safe enough. I have been impressed through my activities at the World Health Organization that we really do have an excellent food supply. There are some problems. But the mere inspection of a product does not guarantee its safety.

The only reason that I raise the chicken versus the fish issue is not for invidious comparisons, but to point out the level of burden of illness between these. I think for food safety this should be done. First, we need a bipartisan governmental program that involves both the administration and the Congress examining what food safety should be, and what the problems are, what is real and what is not real.

I believe we need to involve our great academies, the National Academy of Science, the Institute of Medicine, to focus on the health issues, and where there are health problems, to design a program to address them.

I also believe that we need to restore some of the credibility to spokespeople in government and Academe and the academies and this has to be done on a continual basis. We cannot at a time of crisis have the Commissioner of the Food and Drug Administration say we have just dealt with cyanide and if I was concerned with the problem in Alar and apples I would have used the same authority to remove those from the market. That is not the way to deal with this.

We need an understanding of the next point which is the most important, what risk assessment is. And I guess what I was lamenting earlier with you as I look at the health problems in the land, there is no question that we need to upgrade our program in fish inspection, but on a major scale of where health problems are, I would much rather see the millions of dollars go to some of the people that are not getting nutritious food. I would much rather see some more focus on teenage pregnancy and drug abuse, not to provoke invidious comparisons of who did and who did not do this, but as you ladies and gentlemen in the Senate and House balance the budget, we have real distinctions to make.

Senator COCHRAN. Under current law, is it the obligation or responsibility of the Food and Drug Administration to inspect imported foodstuffs?

Dr. YOUNG. Yes, it is.

Senator COCHRAN. And under this legislation, as I understand our proposed bill, that responsibility would be transferred to the Department of Agriculture at least as it relates to the narrowly defined responsibilities in this legislation; is that correct?

Dr. YOUNG. That is correct. In our inspection——

Senator COCHRAN. Is that one of the reasons why you are opposed to the bill?

Dr. YOUNG. No, it is not, Senator. I tried to examine the action on this as to whether I was opposed to it from self-serving turf issues or medical issues. I did not particularly in my oral presentation focus on the issue. If you were to put 100 percent mandatory inspection of each and every fish in the U.S. Food and Drug Administration's purview, I would argue against that as vigorously as I am here. I just think the program has to match the public health need.

Senator COCHRAN. Mr. Brennan, I noticed that the Department of Commerce currently has certain responsibilities that would likewise be transferred to the Department of Agriculture under this bill. Is that correct? Is that your reading and understanding of the legislation?

Mr. BRENNAN. I was not aware that there would be a transfer. Clearly, the Department of Commerce through the National Marine Fisheries Service has responsibilities for operating the voluntary seafood program. And we also have responsibility for regulating activities of fishermen at sea. And it seems to me that when you are regulating the activities of fishermen at sea, you ought to try to confine your activities to one agency. To have one agency regulating his activity at sea because he is concerned about the cleanliness of the fish he catches and another agency regulating his activities at sea because he is concerned about the time or place of harvesting or the amount of fish he caught because he is concerned about having the fishery resource be available for years, it seems to me that it does not make a great deal of sense to pull those two authorities apart.

By the same token, the only agency that now is in the plant, on a sometimes continuous basis, is the National Marine Fisheries Service inspectors who are in the plant under the voluntary program paid for by the industry. And as we have noticed in the last few years, as the amount of product that we are exporting goes on to record levels, we are finding not only an increased demand for our inspectors to assure domestic consumers of wholesomeness of the fish but also we are finding that more people exporting are finding that they need to have this seal of approval of the National Marine Fisheries Service that will tell the foreign consumer that, in fact, the product has been inspected. Last year we inspected about 500 million pounds of exported product, I believe.

Senator COCHRAN. Mr. Chairman, I have some more questions which I will defer, though, until other Senators have had a chance to ask questions.

The CHAIRMAN. Thank you, Senator Cochran. Senator Daschle.

Senator DASCHLE. Thank you, Mr. Chairman.

Dr. Young, I am a little confused, I guess, with regard to your position as it relates to mandatory inspection where you say you are opposed to 100 percent mandatory inspection. Would you be opposed to mandatory inspection using HACCP principles?

Dr. YOUNG. Not at all. Senator, I think maybe I need to define the term. Mandatory is a government required inspectional program.

Senator DASCHLE. That is right.

Dr. YOUNG. Which stands in contrast to a continuous program which would be a man in the plant program. I am not at all opposed to a mandatory government led program.

Senator DASCHLE. Using HACCP principles.

Dr. YOUNG. Using HACCP principles. This is something that we have used and developed, actually, in low acid canned food approximately 20 years ago. But a program that requires continuous inspection would be a program that I would oppose.

Senator DASCHLE. Continuous inspection. See, that is where I am confused. HACCP principles apply to a certain extent to a continuing inspection; do they not?

Dr. YOUNG. The HACCP principles may or may not require continuous inspection depending on the particular product.

Senator DASCHLE. So you are in favor of the ones that do not provide for——

Dr. YOUNG. No, I am sorry, Senator. I may not have made myself clear.

Senator DASCHLE. Well, that is what I am trying to nail down if we can.

Dr. YOUNG. HACCP principles deal with a hazard analysis of critical points.

Senator DASCHLE. Right.

Dr. YOUNG. Some of those points may be identified as requiring continuous inspection at that point or an audit of records that proper procedures have been followed by industry.

I am trying to distinguish for you that using HACCP procedures, one identifies the critical points and designs the inspection to address them. One does not necessarily need continuous inspection of every product. If it were necessary after Mr. Brennan's folks went through and developed a HACCP principle looking at a particular product, then that would be where the partnership between Government, the States, industry would focus. But it does not necessarily mean continuous inspection is required.

Senator DASCHLE. Would you have any objection to taking the authority for inspection entirely out of FDA and giving it to the U.S. Department of Agriculture?

Dr. YOUNG. Yes, I would. I would because in the experience that I have had in the past 5 years, when there is a problem dealing with food safety, it comes directly over to the Food and Drug Administration and the U.S. Public Health Service, that constellation of CDC, NIH, and FDA. It becomes a medical problem. And, thus, I would not see how to envision a food safety program without that interaction.

Even now, although we do not have the inspection responsibility for poultry, we do collaborate very closely with the Department of Agriculture in that way. So I would not find it appropriate to have the Food and Drug Administration removed from seafood.

Senator DASCHLE. My suggestion would obviously include a very close correlation in your work and USDA's. There would have to be that kind of interface as there is now, as you point out, very appropriately with poultry and with meat. Let me just ask Mrs. Smith. You have 10 times the inspection personnel that FDA does. From my own experiences, I would have to say that it is difficult, and I think you do an excellent job in many respects, but it is difficult even with the personnel you have to maintain the standards in quality for inspection that you ascribe to.

What do you think of the idea of FDA, having substantially less numbers of people, fewer people, to do the people, about their ability to do it under these circumstances?

Mrs. SMITH. Well, obviously both USDA and FDA are playing a different role here, and it would depend on what the criteria would be that you would set up for this type of program. Each has a responsibility, and granted USDA has more personnel, but the system which was set for meat and poultry included that each bird and each animal was to be inspected, and that currently is what is being done, and we will continue to do as we are instructed to do and as science says.

As we look at the future of inspection, and the development of further technology, I see inspection certainly changing to some degree because we have now identified illnesses that we did not know in the past that can be borne by foods. And I see FDA having a role, even though they do not continually inspect anything that they inspect. And there are a lot of other things we help each other on than fish, meat, and poultry.

Dr. YOUNG. Senator, could I add something because I may have left you with a misimpression on this. In the collaborative program between FDA and NOAA, FDA's role would be the setting of standards, and ultimate responsibility for the public health aspects. We would rely on NOAA's inspectional capabilities. We are not looking to set up an inspectional program, but unless either Agriculture or NOAA were to divert resources from other programs, in other words, use, as you describe, the already strained meat and poultry resources to deal with the fish program, someone somehow is going to have to have the increased burden for the inspectional requirements that you are talking about.

My focus has been on FDA's leadership role in establishing standards, the research on seafood safety that we do, the development of HACCP principles in an interactive way with industry. But we would not describe our activities as dealing with continuous inspection. Mrs. Smith is absolutely correct. We do not inspect continuously and the point that I made on the blood banks was to drive that point home. A program that is even more critical, in a sense, is not one that uses continuous inspections. That has been a ruling by Congress as we develop our authorities and by the administration.

Dr. **Crawford**. Could I add something?

Senator **Daschle**. By all means.

Dr. **Crawford**. Let me point out that with respect to the current meat and poultry program, it is not solely a USDA program. It is shared between us and a number of agencies. And the way it generally works and the way we anticipated that this would work is that when inspection programs have gone mandatory, like poultry most recently, we have basically done the hands-on inspection. We have looked to EPA and to FDA for setting of tolerances and standards, and also, a kind of little appreciated fact, advisory opinions on scientific matters like irradiation of food.

Then finally one more thing. All of these agencies, including Commerce and Defense, come together in one committee, an expert committee that is now functioning very well and that has begun to consider HACCP principles for all the foods that we consume in the United States. That is the National Advisory Committee on Microbiological Criteria for Foods.

And secondly, we are now in the process of considering setting up a second committee which is a national advisory committee on chemical contaminants. And there I think they all get together. But I would not see this as a USDA take over or anything like that. It is just that we traditionally have done the hands-on inspection and looked to the other agencies for cooperation.

Senator **Daschle**. Well, I share your view. We had a hearing, as Mrs. Smith recalls, a month or so ago on inspection in the meat industry, and we are very hopeful that we can apply HACCP principles to meat at some point in the very near future. But I do not know how much time——

The **Chairman**. Mr. Brennan, were you trying to say something?

Mr. **Brennan**. Yes, Mr. Chairman, thank you. With your permission, I would like to make a comment on this because I think it is pertinent. I am quoting here from the January 1989 issue of Prepared Foods, and I think these points should be borne in mind. "A system intended to protect seafood safety must be able to cope with the sudden arrival of a trawler loaded with perishable fish at a processor's dock." Then quoting from an official of the National Fisheries Institute, "How can you do something like traditional USDA inspection with a net containing 10,000 fish of differing species? You do not have the luxury of keeping fish in a pen until you are ready to process." And then quoting from a Cornell professor, "Traditional inspection will not address the major public health programs in fisheries. A regulatory program for seafood needs the flexibility to cover very diverse and decentralized sources of raw materials, product forms, processes and types of distribution."

I think we have to keep in sight the fact that we are dealing with a unique industry here. There is an awful lot of little boats out there and big boats harvesting product, bringing it in at odd hours of the day and night, and these are really mobile processing plants, if you will look at it that way, where they are fishing in one area for halibut when the halibut season is on. And then they move down and they go for black cod and then they might be catching flounders. And they are coming into different ports and the product that they are getting is processed differently. All that says to me that you have a unique industry. Do not throw away the expertise that you have with an agency that is familiar with that industry, who knows its problems, and is able to deal with them and has dealt with them over the years. So I think you just cannot look at a system where you are talking about carcass by carcass individual post mortem and ante mortem inspection.

I do not think anybody at this table is suggesting that. The question really is what is the most efficient way to deal with this unique industry?

Senator DASCHLE. But you do not have any objection to applying stringent standards as we might define them with HACCP; do you? I mean the HACCP standards can apply practically to the fish industry?

Mr. BRENNAN. I wholeheartedly support the idea, and I believe that industry does too. But what we are dealing with here is a perception on the part of the public who are paying a relatively high price for fish protein, and they are doing it in many cases because they think it is a healthy food. They are an enlightened public and a knowledgeable public. And they want to have some assurance that the product that they are getting has been harvested in the right place and it was a clean fish when it was harvested and it was processed properly. I do not think anyone disagrees with the idea that we have to have an effective inspection system that will be seen to be effective by the consumers. So I absolutely agree with that.

Senator DASCHLE. Well, the confidence level, as I think everyone would agree, is going down. We do not know the reason specifically in each and every case. But we know they are going down, and in large measure they are going down, as I understand it, because people are very concerned about the lack of inspection today, the lack of standards, the lack of the same kind of commitment to quality that we have in meat and poultry.

Mr. BRENNAN. I think there is one other thing that they are seeing too, and this is why we have to get the States involved. They are seeing a lot of talk about near-shore pollution, and it makes them wonder—not just about the fish that is harvested from those near-shore places. Most of the commercial marine species are harvested in the blue water where there is not the problems they have near shore.

But when they hear about arsenic or chromium or PCB's or pesticides in near-shore waters in the New York Harbor and in various places around the coast, they start thinking, gee, that is where fish come from. Maybe I ought to be concerned. Subliminally they are getting this message, hey, there is a problem here. They want assurances, and that is why we suggest that you have to do more than just look at the fish and smell it. You have to look at some of the constituents in there. Look for PCB's and look for heavy metals in appropriate types of species where you might have that problem.

Senator DASCHLE. Mr. Chairman, I have taken up more than my share of the time. I wanted to get into the CDC study, which seems to conflict fairly substantially with Dr. Young. But we can save that for another time.

The CHAIRMAN. Senator Cochran.

Senator COCHRAN. Mr. Chairman, we have other witnesses and the hour is getting late. Everybody has been very patient. I may have some other questions. I join you in thanking this panel for being a part of our hearing today.

The CHAIRMAN. I would like to ask one question. Mrs. Smith, would USDA have any problem drawing on the expertise of NOAA or anybody else involved in this?

Mrs. SMITH. No, sir, we would not. We certainly would welcome the expertise of those that have experience that we do not.

The CHAIRMAN. Thank you very much.

Mr. BRENNAN. Mr. Chairman.

The CHAIRMAN. Yes.

Mr. BRENNAN. May I make just one correction for the record? I believe I misspoke and said when we inspected 500 million pounds of fish for export. I meant to say 500 million pounds of fish. I am sorry.

The CHAIRMAN. I understand. We have had a lot of numbers going back and forth here today. This is an extremely important issue, and each one of you will get your testimony, so you can check it. I know that everybody has done everything possible to be forthright in what they have said. It is quite possible to get a number off, so when you check your testimony do not hesitate to check it and if you want to expand with additional points feel free to do that. We are not trying to play any kind of games. We just want to put together the best possible legislation so that whatever food and fiber we have in this country will be known as being safe. We want to keep the consumer's trust, so we need to find the best and most effective way to do that. I thank all of you very much for being here.

Dr. YOUNG. Thank you.

The CHAIRMAN. Thank you. Thank you, Doctor.

We will go to our next panel of witnesses. Ellen Haas, the executive director of Public Voice, and Lee Weddig, the executive vice president of the National Fisheries Institute. Both Ms. Haas and Mr. Weddig have spent a great deal of time on this issue, and I want to emphasize especially to both of you what I said at the beginning of the hearing. I thank you both very much for the amount of time that you have taken, not only talking among yourselves, but the amount of time you have taken with our staff and other Senators' staffs, the amount of time with Senator Mitchell and Senator Cochran and everybody else involved with this issue. The fact that you have been willing to take all that time has certainly made my job easier and I hope others easier, too.

Ms. Haas, we will start with you and then go to Mr. Weddig and then we will go to questions.

STATEMENT OF ELLEN HAAS, EXECUTIVE DIRECTOR, PUBLIC VOICE FOR FOOD AND HEALTH POLICY, WASHINGTON, DC

Ms. HAAS. Thank you very much, Senator Leahy, Senator Cochran. It is a pleasure to be here. I would like to summarize my prepared statement.

THANKS AND REMARKS CONCERNING A SAFE AND WHOLESOME FOOD SUPPLY

I would like to begin by thanking you for the leadership and commitment that you have shown to assuring consumers of a safe and wholesome food supply and for recognizing we are not talking about an inflated issue. We are not talking about an issue of perception. We are not talking about a turf battle. We are talking about the inadequacy of current programs to protect the consumer and the critical gaps that do exist in our food safety network so that consumers today do not have the benefit of a safe and wholesome seafood supply.

SINCE 1983 PUBLIC VOICE HAS BEEN DOCUMENTING THE SERIOUS HEALTH RISKS TO CONSUMERS OF THE SEAFOOD SUPPLY

Since 1983 Public Voice has been documenting the serious health risks to consumers of the seafood supply. And most importantly evaluating the inadequacy of the current program which leave consumers vulnerable to acute illnesses, sometimes even death as well as the risks of long-term illnesses such as cancer.

WE HAVE ADVOCATED A COMPREHENSIVE MANDATORY INSPECTION PROGRAM THAT PROMOTES CONSUMER HEALTH

Since 1983, we have advocated a comprehensive mandatory inspection program that promotes consumer health.

FISH INSPECTION

Let me say that nowhere has anyone ever talked about inspecting every fish. Nowhere has Public Voice, or any organization, talked about having an inspector on every boat at every minute. But rather we have talked about a program that would make sense in the 1980's and protect the consumer to correct a long-term gap in food protection.

DRIVEN BY THE PROPER INTEREST

It is our hope that the process is driven by the interest in ensuring a safe and wholesome food supply and we not be driven by public relations approaches to legislation nor to turf battles. And instead that we view this program as a public health, food safety program so that consumers will be assured of the healthful promise that seafood offers.

CONSUMPTION OF SEAFOOD IS UP BY 20 PERCENT

In the 1980's, consumers have heeded the advice of the National Academy of Sciences, the Surgeon General, who have recommended that consumers turn to fish as a low fat protein source. And so from 1980 to 1987, consumption of seafood went up by 20 percent, and we are eating approximately 4 billion pounds.

FISH IS THE ONLY FLESH FOOD NOT SUBJECT TO MANDATORY INSPECTION

Yet the sad irony is that fish is the only flesh food *not* subject to a comprehensive, mandatory Federal inspection program.

The result is that consumers face the risk of acute illness. This concern has grown in the last year as more consumers have become aware of the hidden hazards and as we know, and as you mentioned earlier, consumption went down by 2 percent in the last year.

THE RISKS OF ACUTE ILLNESS FROM SEAFOOD

As we begin this process, I think it is very important to recognize not only is the fishing industry unique, but there are unique characteristics of fish that pose concern for consumers and increase its risks.

First of all, the risk of acute illness from bacteria and parasites is greater in fish and shellfish, which, unlike most meat and poultry, is generally harvested from uncontrolled environments. They are not in a pen. They are not in a slaughterhouse the same way. The waters where fish are taken from may be polluted with sewage, industrial chemicals, or pesticides.

Also, certain types of seafood, particularly shellfish, tend to concentrate contaminants in their tissue. Even when refrigerated, fish and shellfish usually deteriorate quickly. And finally it is important to recognize that a great deal of shellfish and fish are eaten raw.

While there is an honest debate about numbers and Commissioner Young did do a whole lot of magician's work with numbers this morning, I would like to say, too, that——

The CHAIRMAN. I thought you would enjoy that, Ms. Haas.

Ms. HAAS. I did and I did not. Because it gives me great concern to have the head of our public health agency dismissing the real risk and knowing, too, that we depend on our data from the Centers for Disease Control. We all do. The agencies do and the Congress does and consumer and industry. And we depend on consumers reporting to the CDC their illnesses. The CDC says that they only get 1 to 5 percent of all the people who have become ill to have reported it and traced it back to the particular food.

So the evidence is something that we have to take a look at what we have, but realize that we are hampered with the inadequacy. And what we do have according to CDC is from 1982 to 1986 the number of reported outbreaks from fish and shellfish actually exceeded the total reported outbreaks for both beef and poultry combined.

What was not said this morning is that we eat four times as much beef and three times as much poultry. Also what was not said is you cannot take out shellfish from those statistics just like you cannot take out groundbeef statistics from a total illness data.

When you combine the data with USDA food consumption data, you find that the risk of a food poisoning outbreak from seafood is 25 times greater than it is for beef; 16 times greater than poultry; and 16 times greater than pork (see chart B, page 135). Even if you use cases, as Dr. Young suggests, then seafood is 3 times as likely to cause illness as beef, and 1½ times as likely as poultry.

CONTAMINATION OF SEAFOOD FROM POLLUTED WATERWAYS

But what was not spoken about today was the issue of facing long-term risk from contaminants in the polluted waters. Little attention has been given to this critical area. Because pesticides and chemical compounds are present in the waters from industrial and municipal dumping, from agricultural runoff, from pesticide application to shorelines, there is present danger.

Even with the limited data available on chemical contamination of fish demonstrates that the toxins are commonplace in the seafood we eat. Of all the domestic food samples collected and analyzed by the Food and Drug Administration between 1979 and 1985, including vegetables and dairy products, fish had the highest percentage of samples containing illegal residues, 5.2 percent. And what is the government doing about both these acute risks and the long-term risks?

GOVERNMENTAL SURVEILLANCE INADEQUATE

Public Voice is concerned that seafood gets only a hit and miss inspection at best. It is a patchwork of programs between the Federal and State governments, but it is only limited, voluntary and inadequate.

NATIONAL MARINE FISHERIES SERVICE

Let us begin with the National Marine Fisheries Service. That voluntary program is paid for by the users, the corporate users, and is basically a marketing tool. But it has been going down in coverage over the last several years. In fact, today 1987, only 11 percent of our all our fish is inspected under this program.

FDA

The FDA that has authority to inspect seafood in interstate commerce provides just scanty protection. Again, I was not talking about an inspector for every fish, but I would like to see better than what the FDA has been providing. In 1988, for example, they inspected only one-quarter of all the processing firms, seafood processing firms. That means that three-quarters of the processing firms did not even have an inspector or an inspection in that year.

And in no case does FDA ever inspect the vessels who process at sea. When you look at chemical contaminants, and it was good to hear Counsel Brennan just a moment ago, he said that tolerances are important and standards are important for PCB's and dioxin and chlordane. However, FDA has only set one tolerance for PCB's and 13 action levels, though hundreds of chemicals can be present.

And then they test only a very minute percentage of fish for dangerous levels. To me, the fact that we ate 4 billion pounds of fish last year approximately, and FDA only tested 996 domestic and 628 imported seafood samples is appalling when USDA tests 44,000 samples for chemical residues that may be present in meat. And finally shellfish, which we hear presents the greatest risk to consumers, and which the CDC estimates that 1 in 250 consumers will get ill from eating raw shellfish. FDA has a program that is voluntary, that has no effective standards, and in 1987 9 out of 23 of the States were out of conformance. When we tried to get the information from FDA, they said that information was not available to the public for 1988. I am pleased to see that the Commissioner brought it with him today.

MANDATORY FEDERAL INSPECTION NEEDED

What we believe is that we need legislation to address the problems. My testimony goes into the very basic elements that need to be in such a bill. We are pleased that S. 1245 is a beginning step. We look forward to working with you in the future. Let me just say that in four short points that we believe that the application of an inspection program needs to be at all stages of processing from harvesting to packing and transportation.

And that we base it on a standards approach and certification. The authority for the Secretary of Agriculture is the appropriate place to have and administer a comprehensive mandatory inspection program. However, the standards that need to be set for chemical and microbiological contaminants is appropriate to be set by the FDA and that should be given to the Secretary of HHS because they do it now with chemical contaminants for meat inspection as well.

Also, I think it is important that there be an equal program for imported fish, and finally that there be industry recordkeeping. That there be sampling and detention and that there be adequate employee protections as well as a range of civil and criminal penalties. I have gone on very long, and our prepared testimony goes on even longer. We look forward to working with you in securing this essential right for consumers.

[The prepared statement of Ms. Haas and attachments appear at the conclusion of the hearing.]

The CHAIRMAN. Thank you. You have actually taken your time and Mr. Weddig's, but we will not take away his time. One of the other Senators told me that he would withhold questions this afternoon so we could have the time. Mr. Weddig, go ahead, please.

STATEMENT OF LEE J. WEDDIG, EXECUTIVE VICE PRESIDENT, NATIONAL FISHERIES INSTITUTE, WASHINGTON, DC

Mr. WEDDIG. Thank you, Mr. Chairman. I appreciate very much your taking on this difficult task. And as we hear the testimony from the various agencies it becomes more and more difficult to try to sort out what is the right thing to do. We do appreciate also the initiative of your colleagues and yourself for introducing the legislation. Finally, I would like to say that speaking for the industry, that it is, I want to say, a pleasure, most of the time, to be working with Ellen Haas and Public Voice and trying to come to grips with what should be done, what is the right thing to do for the consumer, and of course, from our viewpoint, for the industry as well.

The CHAIRMAN. Mr. Weddig, if you would yield for just a moment. I meant very seriously what I said in my compliments to both you and Ms. Haas in this. You are both people who carry a great deal of credibility to this committee, both of you do. And it makes my job, Senator Cochran's, Senator Mitchell's and everybody else involved in this, much easier to the extent that you are able to find areas of agreement. We can all sit around this table and write a piece of legislation, and each one would be different. And unfortunately it does not work that way. We have to have one with great support. And I said it only in passing at the beginning, and I do want you to understand that I am not simply saying something for the record, I mean it most sincerely. We owe the both of you a great debt in the amount of time you have taken.

Mr. WEDDIG. Thank you.

Ms. HAAS. Thank you.

Mr. WEDDIG. Having said that, I do not want to give the impression that I am going to agree with Ellen all of the time because we reserve our options here.

Ms. HAAS. No one would be fooled.

The CHAIRMAN. I cannot get everybody here to agree with her all the time either, and we do not agree with each other at the table all the time.

Mr. WEDDIG. Mr. Chairman, we have submitted a prepared statement which outlines rather completely our views as to why we think we need an inspection program specifically designed for the seafood products in the industry and what we think belongs in it.

TWO POINTS THAT ARE IMPORTANT

I would like to take just a few minutes to dwell on two points: why it is so critically important for the seafood industry of the United States to get such a program in place and secondly why we think it belongs at the U.S. Department of Agriculture.

THE SEAFOOD INDUSTRY HAS BECOME AN IMPORTANT PART OF THE FOOD SUPPLY

In terms of the importance to the industry and to the Nation, the seafood industry has become an important part of the food supply. It represents about 8 percent of the animal protein at this point in time. It is actually larger in terms of consumption than turkey, than veal, than lamb. It generates consumer dollars in terms of $25 to $30 billion a year in what consumers pay for seafood products in the United States. So it is an important part of our economy. And directly and indirectly it generates a million jobs. So it is important as an employment base particularly in coastal communities which may not have other things, other places for people to work.

And it is a growing part of our export of food in that we now are the world's largest exporter of seafood. We have outdistanced Canada as an exporter. The dollar value of our seafood exports now exceeds $2 billion a year. So it is important from that perspective as well.

SLUMP IN CONSUMER CONFIDENCE

The vibrancy of our industry, which has been very vibrant indeed for the last 8 years, is now threatened because we have had a slump in consumer confidence over the last 2 years. There is a cloud that has been thrown over the ability of our industry to grow and to serve the consumer. Some of the reasons are very real. And they include such things as the vibrios in some of our oyster stocks, the histamine poisoning in some of the finfish problems, the ciguatoxic problems that we have in the tropical areas. And we also have this nagging cloud which was mentioned before about what does pollution in our coastal waters really mean.

PERCEPTION CAN BE MISCONCEPTION

While it has not been shown that this is, indeed, a health hazard, there is a suspicion, as Jim Brennan said before. And in addition, we have perception. There is misconception at times as to just what some of the numbers mean, what exactly is the problem, if there, indeed, is a real problem. I think back to a situation that would, I am sure, not be pleasing to Senator Cochran. There was a group awhile back that put out a publication that said, well, avoid catfish. And the reason was they had seen some report where catfish taken, I believe it was out of Green Bay, Wisconsin, which was in Lake Michigan, a polluted area, and it was found to contain some pollutants.

But not knowing that 99.9 percent of the catfish on the market comes from farms the advice was "do not eat catfish." It took a long time to clear that up. But this is the type of perception that can get loose and can create real problems for an industry and for the consumers because seafood is also important to the consumers, and as Ellen said, it does have unique properties, unique nutritional properties.

If you saw this morning's Post health section, you may have seen the most recent report. It was a condensation of a research that was published in the British medical journal Lancet, and it showed that the use of only two servings of fish a week had a marked effect on people who had suffered heart attacks and reduced the number over any other diet of those who suffered a second heart attack.

And I think this unique property of fish, the omega-3 acids that are present in fish and fish alone, are important to consumers and to the health of the country. And we would really feel that it is important to make sure that consumers have confidence in seafood so that they can make fish an important part of their diet because just as poultry and meat are important, fish should be in people's diets as well.

REASONS WHY WE THINK INSPECTION SHOULD BE IN USDA

Looking at the reasons why we think inspection should be in USDA, there is a synergism there in that the infrastructure is in place, the managerial capabilities, the economies of scale of having a force of 7,000 or 8,000 inspectors out there in the plants. To add to that those necessary people to take on the 2,000 or 3,000 plants that are involved in the seafood industry seems to make the most sense.

OVERSEAS ACTIVITIES

Les Crawford mentioned the overseas activities. We do import from 80-some countries on a regular basis, and having the ability to survey those operations overseas is important and agriculture has the people there already. Our export business, as I mentioned, also demands interaction with the overseas countries because just as we want to make sure that the product that we import from overseas is safe, the nations overseas want to make sure that our product is safe.

And we are already running into difficulties with that. And Senator Gorton, as an example, would be much concerned because the crabmeat that would be processed up in Washington State going into Canada will now have to be inspected at the port-of-entry, at the border by the Canadian authorities because we do not have an inspection system.

Yet the Canadian crabmeat, the same product, coming back flows into our country without any impediment because Canada does have an inspection system. The same thing is going to happen in Europe in 1992 as the Common Market comes together. And even Senator Harkin from Iowa, you might not think that Iowa is a seafood producer, but we export carp from Iowa to Germany, and when 1992 comes around we want to make sure that that product can move into the Common Market without being stopped at the port-of-entry over there.

AQUACULTURE

But there is more to it than this of having a specialized system already in place for animal proteins and the ability to move it into the fish area as well. And that is the growing nature of fisheries that is becoming part of agriculture itself. Aquaculture now represents 12 to 15 percent of the volume, of the total production in the United States. It represents 17 percent of the value. The aquaculture production of 600 million pounds a year tripled over 10 years' time. This production in aquaculture now is greater than the entire production in New England.

In other words, our farms are putting more fish into the marketplace than all of the catch in New England at this point in time. Catfish alone is 1½ times the production of all the cod, all the haddock, all the flounder, all the ocean perch, and all the pollock combined. And as startling as the growth of aquaculture has been, it is going to be even greater.

FISH AND AGRICULTURE ARE INTERTWINED

We predict that in 20 years time it is going to represent at least 25 percent of our total usage in the United States. So fish and agriculture are intertwined. They are going to move forward being more and more intertwined, not only in the production, but in the use of feeds. We have the specialized agency in the USDA to handle animal protein inspection. It makes good sense in our minds that that should be the agency to do it for fish, too, as an inspection system is developed.

Mr. Chairman, I would be happy to answer any questions.

[The prepared statement of Mr. Weddig appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you very much. I note, Ms. Haas, your testimony said that FDA should set the standards for chemicals and the microbial standards. FDA does not set the microbial standards for meat and poultry. The standards are difficult to set. You get a widely varying infection level and microbes are alive and they do grow. How would you feel about FDA and EPA setting the standards for chemicals or pesticides and USDA setting the microbial standards?

Ms. HAAS. To begin with, as you said, FDA and EPA would be the appropriate place to set them for chemical contaminants. So I would feel that is positive. On microbiological, we have had a sorry history on being able to set those standards for poultry, as you well know, and we applauded your efforts last session to introduce the Safe Food Standards Act.

We think that there is one approach that the National Academy of Sciences, with their expertise, could identify those contaminants that are appropriate for setting of standards and that FDA with their science background could do that methodology and that kind of standard setting. They have the better resources to do that than do the Department of Agriculture. And it is a separate issue from the overall operation, which is what agriculture's real expertise is in. The size and scope and operation of an inspection program is most appropriate for USDA.

But the science part of it would be most appropriate with FDA, which is a very small part, but an essential one to make the program work.

The CHAIRMAN. Mr. Weddig, in your testimony you said a new regulatory scheme must specifically address the problems of ciguatoxin, scombrotoxin and the unique natural toxins, bacteria and viruses at times found in mollusks.

Now it sounds an awful lot like a call for microbiological actions or tolerance levels. How would you see that working?

Mr. WEDDIG. Well, there are really two different problems in that the pathogens that would be found in mollusks are of environmental origin. They could either be paralytic shellfish poisoning type problems which come from algae outgrowth or they could be the products of contamination or pollution, I should say, of growing waters.

The system is in place to take care of those problems. It really addresses the quality of the water in which the animals are growing. Growing waters are either closed or kept open, depending on the monitoring of those beds. The problem there is one more of intensified monitoring and enforcement rather than any new great system. It just needs to have more effort and more research to try to develop a better method of determining the safety of some of the growing waters because many of the new things we are seeing, some of the pathogenic viruses especially, are not detected in the old-fashioned way, the ones that have been used for years and years.

The present system was structured in 1925, and so now there is a major research project underway to come up with a better method of determining the indicator organisms to make sure you really are classifying the waters as either being safe or unsafe. Now in respect to the scombrotoxin or histamine poisoning, that is due to mishandling at some point along the way. That is a product of decomposition, and so here we would see that the answer to that has to be the HACCP program which is looking at the way the product is being handled from the time it is pulled from the water through the distribution system.

Because if these particular types of fish decompose to any extent they can throw off this histamine build up which is going to be causing illness for some people who are susceptible to it. But that is a HACCP type of an operation, and the molluscan growing waters is a harvest waters monitoring situation—two different problems.

The CHAIRMAN. On the critical control point studies you have been conducting, do they show a need to look at harvesting vessels? The reason I ask is that in your testimony you call for inspecting processes first and then going to the harvesting vessels if needed. What did the critical control point study show about harvesting vessels?

Mr. WEDDIG. It really depends on the species that is involved in the type of processing that is going to take place, in that you have certain species in which the harvest time is very brief, a day boat, as an example. And there is relatively little that can go wrong on the boat when it reaches the processing plant.

So your first critical control point would be the incoming raw material inspection, which will determine whether it has been properly iced during the period of time that it has been out there. If you have a hazard with a given type of fish, and I am thinking here now of, say, the reef fish in the tropical areas where you have the potential of ciguatoxin. It has nothing to do with the handling of the product. It rather has to do where you caught it. Now your hazard control point would have to be some regulation of the fishing ground itself just to keep people from fishing in areas where there is a susceptibility to ciguatoxin outgrowth.

So each specie has to be looked upon separately, but in the large, we think that most of the products can be handled by having the first critical control point at the incoming raw material inspection.

The CHAIRMAN. Ms. Haas, how do you feel about that?

Ms. HAAS. Well, I come at it a little bit differently. I believe if you set the standards, you develop a program of prevention, and if you certify the fishing vessels, which is the approach that we would support, and you make sure that those fishing vessels have icing facilities, refrigeration, that they are clean and sanitary, you are going to avoid problems like scombro-poisoning because the fish was thrown up on a boat, and it was not iced and the histamines formed.

That means, then, that you would just have the certification and the standards, and you would not have continuous inspection or anything like that, and that is the approach that we think makes sense.

The CHAIRMAN. Mr. Weddig, you mentioned Iowa, and the percentage of carp. When I thought about it, I gave Senator Daschle from South Dakota a note asking him how his ocean front industry is doing, sort of like mine. But a lot of us who do not have any access to the oceans are still involved in one form of aquaculture or another. What were the percentages or what was the amount of carp that you said is exported from Iowa?

Mr. WEDDIG. It is a relatively small amount of carp. There is one production area in the northwest corner of Iowa, though, that does produce carp that is prized in Germany.

The CHAIRMAN. But the point is, you have overall, I think you said something about $2 billion of our fish industry product is exported. And I would assume that some of that is value-added product, too; is it?

Mr. WEDDIG. Yes, we do export——

The CHAIRMAN. What I am getting at is that there are a lot of jobs involved.

Mr. WEDDIG. Correct. We export a fair amount of value added, fully processed shrimp into Canada, as an example. And much of the crabmeat that goes into Japan would be fully processed.

The CHAIRMAN. And the only reason I bring that up is again to emphasize a point you have already made. Not only is it important to this country to be able to export agricultural products, however defined, food and fiber. One of the best ways we have of exporting is not just price but also the realization of the importing country that if it is marked "USA," the product has a mark of quality on it. We have seen in a lot of things, not even in your industry, but in the grain and other industries, that when there is a question of whether aflatoxin, or anything else, has been found business can be hurt badly.

Countries import and base their decision not only on price, but on the quality. We are going to be up against some major competitors in the coming years, and I think it is a good point to keep on stressing over and over and over again, whether the hearing is here or in any other committee, that it is a lot easier to export the product when we can assure its quality.

Mr. WEDDIG. That is true.

The CHAIRMAN. I am glad you raised that particular issue.

Mr. WEDDIG. Senator, it is absolutely correct that we have to be able to assure quality to have good export markets. The interesting thing in the past has been that the questions over quality overseas usually arise in a falling market. And that seems to evoke all sorts of concerns over the quality of that shipment that is checked at the dock overseas.

The CHAIRMAN. I understand.

Mr. WEDDIG. But the availability of an effective, respected inspection system will help us get rid of those spur of the moment questions over quality because they would be less likely to be accepted.

The CHAIRMAN. Exactly, and I realize there are times, of course, that quality has a lot to do with everything from internal politics to demand.

Also we have testimony from C. Manley Molpus of the American Meat Institute which will be placed in the record.

[The prepared statement of Mr. Molpus appears at the conclusion of the hearing.]

I thank both of you for being here, and I also thank you for all the work you have done.

Ms. HAAS. Thank you so much.

Mr. WEDDIG. Thank you, Senator.

The CHAIRMAN. Thank you.

[Whereupon, at 4:30 p.m., the committee adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

APPENDIX

PREPARED STATEMENT OF JO ANN SMITH, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mr. Chairman, on behalf of the U.S. Department of Agriculture, I appreciate having this opportunity to testify today on S. 1245, a bill to establish a comprehensive fish inspection program.

Consumers are looking for a program that will assure them that the seafood they eat is safe, wholesome, and properly labeled. Many consumers might be surprised to learn that most seafood currently is not under mandatory inspection. Up until 1956, a voluntary fish inspection program under the Agricultural Marketing Act was located at USDA. The voluntary program is now operated by the National Marine Fisheries Service under the Department of Commerce.

With the understanding that the administration still has this issue under review, I would like to discuss today how the U.S. Department of Agriculture might be able to implement a mandatory fish inspection program that would provide those assurances to consumers.

Mr. Chairman, the experience of incorporating and administering a new inspection program would not be new to FSIS. Years ago, after the voluntary poultry inspection program was made mandatory by Congress, the agency successfully combined the separate meat and poultry inspection programs into a single, strong inspection system.

A fish inspection program could build on USDA's existing meat and poultry inspection operations. As you know, USDA's Food Safety and Inspection Service (FSIS) currently has a Federal inspection force in place at meat and poultry slaughtering and processing plants around the United States. These inspectors are present in every meat and poultry plant in the United States that prepares product for distribution in interstate or foreign commerce.

Currently, this field staff consists of approximately 7,000 inspectors and 1,200 veterinary medical officers. Each and every one of these employees is required to attend educational sessions at the FSIS training center in College Station, Texas. Depending upon the duties that will be required of the employee, the training may last from several weeks to several months, and may include classes ranging from "On-line Slaughter Quality Control" to "Basic Processed Food Inspection." Supervision and management classes are also required. When changes occur in inspection procedures, or an employee is promoted or given additional responsibilities, continuing education classes are required, either through formal classroom training, correspondence courses, or by using the extensive video training tape library maintained at the training center.

FSIS inspection personnel are backed up by a strong supervisory network consisting of 5 regional offices located around the country; 26 area offices; 189 inspection circuits; and, of course, the headquarters staff here in Washington.

To complement the field work, FSIS also has extensive laboratory capabilities. Three state-of-the-art in-house laboratories, 2 contract laboratories, and 315 accredited private laboratories all have extensive experience analyzing for chemical residues, microbiological contamination, processed product composition, and economic adulteration. Such laboratory facilities could be helpful in meeting the requirement under section 502 of S. 1245 of establishing "an inspection program designed to ensure the safety and wholesomeness of fish and fish products."

FSIS has a long and successful history of evaluating the microbiological and chemical safety of meat and poultry that could be beneficial in developing a fish inspection program. FSIS is committed to basing its regulatory decisions on scientific information. During FY 88, over 2.1 million analyses were completed on nearly 500,000 statistically selected samples.

But laboratory analysis is not the only way or always the best way to monitor food safety risks. Evaluations of safety and wholesomeness must be made, particularly when the risks of decomposition and mishandling are present. The importance of a system for inspection designed with emphasis on *preventing* rather than detecting problems must also be recognized.

Seafood is very perishable, and delays in processing or processing under unsanitary conditions can markedly increase the potential for health-related problems. The framework for determining real versus perceived processed seafood risks must be developed. There is often not enough time to conduct laboratory analyses, and, where warranted, minimizing risks from perishability may require an in-plant program.

Several "rapid tests" for meat and poultry have been developed by FSIS scientists and are conducted in the plant by an inspector, with the results being available almost immediately. In FY 88, over 1.2 million rapid test analyses were completed from approximately 250,000 samples. These rapid tests are used to determine such things as whether certain drugs or chemicals are present, if a product was canned and cooled properly, or if a different species has been used than is indicated on a label. Some of these types of tests could be developed for fish and seafood.

Section 502 of S. 1245 establishes the proposed scope of a fish inspection program. Many of the provisions of section 502 are activities that FSIS has experience in from meat and poultry inspection programs and could be expanded to include fish and seafood.

For example, under section 502(b)(1), the inspection program is to "cover the processing, storage, and handling of meat from fish and fish products." One of the best ways to meet that requirement is by using the Hazard Analysis Critical Control Point (HACCP) "systems" approach. FSIS has already incorporated HACCP procedures into certain aspects of our current processed food inspection operations, and is preparing for the implementation of HACCP-based inspection programs across-the-board.

It is widely agreed that the HACCP approach is best for fish and seafood inspection as well, with the exception of molluscan shellfish. With HACCP, requirements focus on points in the slaughtering and food processing stage where food safety problems are most likely to occur—whether it is during manufacturing, while in storage, or at any point where the product is handled. Methods are then developed to "control" those points and assure that a hazardous product is not produced.

Another important element to be considered as part of a fish inspection program is found under section 502(b)(2), which requires that inspection of imported and domestic fish products be on an equal basis. FSIS already has a strong import inspection program in place that could be modified to include seafood. We currently evaluate imported meat and poultry products to determine whether they comply with inspection and other requirements at least equal to those applicable to domestically prepared products.

FSIS' International Programs staff reviews foreign inspection systems to ensure that they are at least equal to the programs required for U.S. producers under the Federal Meat and Poultry Products Inspection Acts. The International Programs division also conducts reinspection of imported meat and poultry products through a network of 75 inspectors at points of entry to the United States. They also represent U.S. interests throughout the world to minimize regulatory impediments to trade in meat and poultry products. In addition, FSIS coordinates the inspection and certification of meat and poultry products for export abroad.

The fish industry is heavily trade dependent, with 60 to 70 percent of fish and fish products imported, and 30 to 40 percent of the U.S. catch exported. There are approximately 40 agricultural attachés and counselors in different countries that USDA utilizes to facilitate trade.

Section 502(b)(3) would provide for registering and inspecting facilities and vessels that process fish products. This provision is similar to FSIS' current application for inspection, blueprint approval and preoperational inspection programs. Under these programs, meat and poultry plants must apply for approval to operate and to receive an inspection number. Prior to being granted Federal inspection, meat and poultry plant facilities and equipment are inspected to ensure products will be produced in a clean and sanitary environment. Extensive and rigorous standards have been implemented and are strictly enforced both before and after inspection has been granted.

Section 502(b)(4) requires the identification of "geographic areas producing fish and fish products that exceed the safety standards developed in accordance with this title." We understand that the intent of this section is to recognize that many States already have fish inspection programs in place, and to work with those States to ensure there is no duplication.

We strongly believe that individual States should have a large role in the inspection of seafood, just as they do now in meat and poultry plants operating solely in intrastate commerce. Currently, FSIS conducts a unique Federal-State cooperative program for the meat and poultry inspection program that provides 50/50 funding to the States if their inspection programs are at least equal to Federal standards.

In addition to cooperative efforts at the plant level, States should be encouraged to take an active and lead role in monitoring and controlling the pollution level in waters used for raising and harvesting seafood. This may be the only feasible way to ensure the safety of molluscan shellfish. At any one time during any given year, a third of the shellfish harvesting grounds are closed due to poor or polluted water.

A strong, cooperative residue program should also be considered between Federal and State governments so as to regularly inspect not only for contaminants from rivers, streams and estuaries, but also contaminants that could occur at sea, such as from heavy metals. States may also be better suited for inspections at ports of entry to ensure registration. In any event, the States do have a very important role to play in fish inspection, just as the 28 States maintaining meat and poultry programs do presently.

Current standards and regulations for meat and poultry could be modified to include fish and seafood to meet the "Standards" requirements under section 502(c) of S. 1245. One area identified in this section deserves particular attention, however, and that is labeling.

A labeling program similar to FSIS' could help reduce the confusion among consumers of fish and seafood as to exactly what they are purchasing, as well as to help prevent fraudulent practices. FSIS' Standards and Labeling Division reviews labels prior to allowing their use.

Label approval applications must include the product name, formula, method of preparation, type of container, and how the label is to be used. A number of labeling requirements apply across-the-board to all meat and poultry products. These include: appropriate product name; ingredients used listed by weight from most to least; net quantity of the package contents; name and address of the manufacturer, packer, or distributor; the USDA mark of inspection; and any special care or handling instructions, such as "keep refrigerated." In addition, label photographs or artwork depicting a product must not be false or misleading.

FSIS's compliance force could also be cross-utilized in a fish inspection program to meet the requirements under section 503 of S. 1245. A geographically dispersed compliance staff of approximately 130 compliance officers explains inspection and other requirements to industry officials, reviews records, and maintains a nationwide monitoring program of inspected products in commercial channels in order to prevent adulterated or misbranded meat and poultry products from reaching consumers.

The compliance field staff, as well as the Washington staff, also investigates violations of inspection laws; controls violative products through detentions, civil seizures and voluntary recalls; and assures that appropriate criminal and administrative sanctions are carried out.

The research and education activities—such as those authorized under section 504—would be important for any inspection program. There are many sources of risk to the consumer from fish and seafood—bacteria, viruses, natural toxins, parasites, chemical contaminants, decomposition, and mishandling.

Just as in meat and poultry, it is not possible for inspection to totally prevent all of these in uncooked or raw products. Even so, a good inspection system could virtually eliminate inplant decomposition and mishandling, and minimize most of the other risks. We must recognize, however, that many seafood products do not pass through plants.

The last four risks mentioned—chemical contaminants, decomposition, parasites, and mishandling—are all areas in which the current USDA meat and poultry inspection program has had considerable success in limiting any possible danger to consumers. These risk areas have been the focus of more frequent on-site inspection for meat and poultry. Additional applied research in the areas of processing, evisceration, and decontamination procedures may be needed, as well as automated equipment for seafood processing and inspection.

Microbiological contaminants are well controlled in cooked, ready-to-eat meat and poultry products. FSIS routinely monitors for these contaminants and imposes microbiological "criteria" to ensure that pathogenic bacteria, namely Salmonella and *Listeria monocytogenes* are not present in these products, which can be consumed without further thorough cooking. The same type of monitoring programs are already being applied to ready-to-eat fish and shellfish products.

Consumer education and outreach would be an important element of seafood inspection, just as it is for FSIS' meat and poultry programs. FSIS directs a comprehensive public information and education program on issues such as food safety, food handling, and labeling. FSIS also develops and distributes written and audiovisual materials for a variety of audiences. USDA's Extension Service is an essential element for reaching consumers down to the county level, and it is used frequently by all agencies within USDA.

FSIS also staffs a meat and poultry "hotline" with home economists, who provide food safety information to callers. In FY 88, over 50,000 calls were received on subjects ranging from safe storage and preparation of foods to microbiological residues. The hotline staff already receives calls on fish and seafood from consumers, the media, etc. requesting information similar to that for meat and poultry.

Finally, section 505, Interagency Cooperation would be essential to setting up a strong, workable fish inspection program. There is a great deal of expertise about fish inspection within other Federal and State agencies. All of that expertise and cooperation would be needed, and USDA would have no hesitation to ask for it.

Mr. Chairman, at this time, the administration does not support any new seafood inspection legislation. Until we complete our review of how best to ensure seafood safety, the administration has no position on whether or not an expanded fish inspection program is necessary, or which agency should manage any program that Congress might establish.

One alternative that the administration will consider, however, is a mandatory fee-funded seafood inspection program under the jurisdiction of the Department of Agriculture. As far as the cost of such a program, our initial analysis is incomplete.

Mr. Chairman, this concludes my prepared testimony. I would be pleased to address any questions that you may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Office of the Assistant Secretary
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Washington DC 20201

STATEMENT
BY

FRANK E. YOUNG, M.D., Ph.D

COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

October 24, 1989

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman,

I appreciate this opportunity to testify today on the Federal seafood safety program. The Food and Drug Administration has decades of experience with seafood as part of its mandate under both the Federal Food, Drug, and Cosmetic Act to assure the safety of the food supply and the Public Health Service Act to prevent the spread of communicable diseases. Our presence here today is reflective of a growing interest--both within and outside the Congress--in understanding just how safe seafood really is, and in examining whether the current Federal seafood program needs to be enhanced or even radically altered--even to the point of moving it out of the Public Health Service. I hope that my participation in this discussion will help shed some light on these important questions.

Unquestionably, new challenges posed by changes in consumer consumption patterns, emerging technologies such as biotechnology, aquaculture and changes in packaging, and a host of existing and potential environmental concerns, both naturally occurring and man-made, necessitate that our seafood safety program be dynamic and responsive to the times. In recognition of these challenges, Phase III of FDA's Plan for Action to prepare the Agency for the 21st century, which we issued in May 1989, calls for us to review our seafood safety activities, including domestic inspection practices and import sampling, surveillance monitoring, research, and consumer education to assure that we are prepared to deal effectively with these matters well into the future.

This statement will address the adequacy of FDA's seafood safety program, the challenges that it faces and how it could evolve in the future. FDA's solid scientific base, both in terms of expertise and laboratory capability, should continue to form the foundation for a successful program.

BACKGROUND

In his 1988 Report on Nutrition and Health, then Surgeon General C. Everett Koop recommended that people reduce fat consumption by choosing foods relatively low in fat, such as fish. Health advisories like this undoubtedly played a part in the rise in per capita annual consumption of seafood from an estimated 12.7 pounds early in this decade to a reported 15.4 pounds in 1987. And with as many as 300 potentially edible species of fish landed by U.S. fisheries, there is still room for considerable expansion. Additionally, the international trade in finfish and shellfish has increased dramatically.

There is a countervailing trend, however, characterized by a reported drop in finfish consumption last year, that must be taken into account by government regulators and industry alike. While we have no hard information to support this claim, some speculate that it may be related to consumer perceptions about the safety of the product. The drop in consumption may also be a reaction to seafood prices. However, medical wastes washing up on coastal shores, ocean dumping of toxic wastes, chemical runoffs into lakes and a host of other environmental and related concerns, including recent oil spills, appear to be contributing to a lowering of public confidence in the safety of seafood. Claims that seafood is many times more likely to cause food poisoning than meat or poultry fuel this trend.

From our perspective, it is critical that we provide assurance of seafood safety to the American public through sensible, cost-effective regulation. Consequently, the basis for our regulatory program is our understanding of what the actual health risks are now and how they may change in the future, as well as their severity and their likelihood of occurrence. In this way we direct our energies in the most effective and efficient ways possible to assure the continued safety of seafood.

WHAT THE DATA TELL US

The main source of data regarding illnesses caused by seafood is the Centers for Disease Control (CDC). In summary, CDC data indicate that seafood does not cause illness in alarming amounts or diversity, and that the major causes of known seafood-related illnesses are limited to consumption of a few species harvested from identified waters, or from consuming raw or undercooked products.

Cases of illnesses linked to seafood also amount to a small percentage of the total number of reported cases of foodborne illness. According to CDC data from 1973 to 1987, shellfish accounted for 2.8 percent of all cases and finfish for 2.2 percent of cases, for a combined total of 5 percent.

Perhaps the best way of putting these figures into perspective is to compare cases involving illness from seafood to those involving poultry and beef. There are two ways in which we may make these comparisons. The first way relies solely on CDC's data on reported cases. There are significant limitations to these data, however, because CDC only receives information about outbreaks that account for a small portion of illnesses that occur. Nonetheless, CDC's data do indicate that finfish and shellfish together are one-and-a-half times as likely to cause illness as poultry and three times as likely as beef. Significantly, however, if cases of illness from raw shellfish are deleted from the comparison, the risk from the remaining seafood becomes equal to that from beef and somewhat less than that from poultry.

The second way to make this comparison is to try to compensate for the underreporting by augmenting CDC's data with best available estimates. Scientists at our Center for Food Safety and Applied Nutrition (CFSAN) recently developed an analysis of risk, based on best available estimates of actual cases of disease. CDC has concurred with the validity of this approach, as well as with the assumptions and data on which the risk analysis was based, and has agreed that the rank order of risk attributed to various foods as a result of this analysis is the most probable one in the United States. (Moreover, the National Academy of Sciences is using this risk assessment as part of a study it is conducting on behalf of the National Oceanic and Atmospheric Administration on the causes and frequency of seafood illnesses, among other things.)

Due to data considerations, the risk assessment compared fish to chicken only. The results indicate that chicken is approximately 200 times more likely to cause illness than fish other than raw or partially cooked molluscan shellfish and approximately 100 times more likely to result in death. Both of these comparisons were on a pound-for-pound consumed basis.

The risk assessment also compared raw and partially cooked molluscan shellfish to chicken. It found that these shellfish are approximately 100 times more likely to cause illness than chicken and approximately 250 times more likely to result in death than chicken, although deaths from raw and partially cooked molluscan shellfish are almost exclusively limited to persons with cirrhosis who consume shellfish contaminated with the _Vibrio vulnificus_ bacterium, a naturally occurring marine organism.

With the noted exception of _Vibrio vulnificus_, there has not been a single outbreak of shellfish-borne illness traceable to clean waters, that is, to waters that were properly classified. Illnesses usually result from harvesting from "closed" contaminated waters or from waters that have been improperly classified. Also, the risk can be reduced dramatically by proper cooking and handling.

Clearly, both the CDC data and the risk assessment show that eating raw or partially cooked molluscan shellfish poses a higher risk on a weight-consumed basis than exists from eating many other types of foods, including virtually all other types of seafoods. Even so, based on the data, FDA and CDC also agree that on a per weight-consumed basis, fish is a safe source of muscle protein. Moreover, seafood consumption has risen approximately 20 percent in the past decade but there is no suggestion whatsoever from either the outbreaks or individual cases reported to CDC that any increase in seafood-related illness is occurring. These data actually show that the numbers of outbreaks and cases are decreasing relative to seafood consumption.

We must guard against complacency (especially in light of the data involving raw or partially cooked molluscan shellfish), however, for without constant vigilance, the potential for a much larger problem exists. We must continue to understand and monitor the potential sources of health risk associated with seafood, and to be especially mindful of the ways in which industry growth and technological innovation could affect those sources of risk or create new ones.

SOURCES OF RISK

1. Bacteria

Because bacteria either naturally live in, or can survive in, aquatic habitats, there is a large number of pathogenic bacteria potentially associated with seafood, particularly molluscan shellfish. Many of these bacteria are far more harmful to specific human sub-populations, such as the elderly, immuno-compromised, or persons with specific underlying diseases, than to the population as a whole. These sub-populations are increasing, however, thanks to successes of modern medicine. Therefore, the concerns about bacterial contamination of seafood, particularly molluscan shellfish consumed raw, are increasing.

In the U.S., 4.4 percent of botulism outbreaks have been attributed to seafood. The predominant type of botulinum in aquatic environments is the kind most readily destroyed by heat. Thus many types of processing can negate the risk when done properly. Nonetheless, with the trend toward modified atmosphere packaging (i.e., the exclusion of oxygen) of refrigerated foods to enhance shelf life, both industry and regulators should recognize that outbreaks resulting from time/temperature abuse could still occur.

2. Viruses

Several viruses infectious to humans enter aquatic habitats through sewage. Most concentrate in shellfish and can be present and infective even when bacterial indicators of fecal pollution are absent. Viruses probably cause the bulk of seafood-associated disease, particularly the Norwalk agent, which is linked to the consumption of raw or undercooked shellfish. The vast majority of shellfish-associated viral disease cases are characterized by a rapid, acute onset and are of short duration and never fatal. Many cases probably go unnoticed or are passed off as "the twenty-four hour bug." A notable exception is hepatitis A virus which is potentially, but seldom, fatal.

3. Natural Toxins

Problems associated with naturally-occurring toxins in fish and shellfish have been recognized for centuries. Ciguatera poisoning is perhaps the most significant problem associated with natural toxins. The toxins are produced by certain microscopic organisms called dinoflagellates, and are transmitted to humans through the consumption of finfish that feed on the dinoflagellates. The larger, more predacious reef fish (grouper, snapper, barracuda, Spanish mackerel) are generally more likely to contain ciguatoxin. Since the toxin is heat-stable, cooking does not make the fish safe to eat.

On the average, 76 cases of ciguatera poisoning are reported annually in the U.S. Three deaths have been reported since recordkeeping began in the 1960's. Because of the types of fish involved, Ciguatera is geographically localized, with the majority of illnesses reported from tropical or near tropical areas including Hawaii, Guam, Puerto Rico, and the Virgin Islands.

Other types of dinoflagellate blooms, such as those that cause the well-known phenomenon "red tide," constitute a public health problem because of their unpredictability and the rapidity with which toxic concentrations may develop. Blooms occur on all coasts of the U.S. These toxins can affect shellfish as well as some finfish. The only available public health measures are surveillance and closure of harvest areas.

4. Parasites

Parasites such as the anasakin nematodes (round worms) naturally infect many fish and ocean mammals. Human infections almost always occur from the consumption of raw fish (sushi, sashimi) or undercooked fish. On average, probably no more than five cases occur annually in the U.S. These could be completely avoided by adequate cooking or by prior freezing of the fish if it is to be consumed raw. FDA developed and distributed to states and others the parameters for freezing fish that will destroy these infective worms.

5. Chemical Contaminants

The presence of toxic chemicals in the aquatic environment leads to the potential for contamination of fish and shellfish. These chemicals include pesticides, other industrial chemicals (such as PCB's), heavy metals (such as lead, cadmium, and mercury), petroleum hydrocarbons, and radionuclides.

Marine species, especially deep sea varieties, comprise the majority of seafood consumed in this country. Generally speaking, this seafood has little potential to contain chemical contaminants at levels of toxicologic concern (methyl mercury is the exception to this general rule). Fresh water species, especially non-migratory bottom feeders, are generally the most exposed to a variety of chemical contaminants. Most of the problems with fresh water fish have been associated with inland or estuarine waterways known to be generally polluted. Many of these waterways are presently closed to commercial fishing or harvest, usually through actions by the states.

6. Decomposition

Fish flesh is more prone to decomposition than are terrestrial muscle protein sources. Decomposition is largely an economic and esthetic problem, significantly shortening the marketable life of fresh seafood. However, one specific type of decomposition leads to human illness. Bacteria associated with certain species form histamine and other heat stable amines that cause scombroid poisoning. Scombroid poisoning usually has a very rapid onset, so the association with a particular fish meal is easy to make. On the average, 65 cases are reported annually in the U.S., although mild cases probably go unreported. Almost all cases of scombroid poisoning are due to fish that have not been stored at proper temperatures before cooking or processing.

The three fish most typically associated with complaints by consumers of decomposition are tuna, mahi-mahi, and bluefish. Bluefish are principally a recreationally caught fish. Mahi-mahi is principally an imported species and is controlled by import alerts from FDA headquarters to its investigators nationwide, and by the imposition of automatic detentions at ports of entry of products from chronically violative sources. Tuna is the subject of joint inspectional attention by FDA and the National Marine Fisheries Service of the Department of Commerce (NOAA Fisheries).

7. Mishandling

As the General Accounting Office (GAO) pointed out in its 1988 report on seafood safety, contamination of seafood often occurs through improper handling and preparation in homes and restaurants. Proper handling and cooking of seafood will prevent many seafood-related causes of illness.

In summary, seafood has the potential to cause public health problems depending upon, as the GAO noted, the species consumed and upon:

- how the seafood is prepared;
- whether the seafood is consumed raw or undercooked;
- whether biologically produced chemicals, such as ciguatoxin and scombrotoxin are present; and
- the quality of the harvesting waters.

FDA'S SEAFOOD PROGRAM - AN OVERVIEW

All of these factors must be taken into account in order for FDA to target its seafood safety program in the most productive ways and to recognize areas in which changes and solutions to new problems are needed.

The primary authority for FDA's seafood safety program is the Federal Food, Drug, and Cosmetic (FD&C) Act, which charges the Agency with assuring that foods, including seafood, are safe, wholesome, and not misbranded or deceptively packaged. The Agency also has authority under the Public Health Service Act to control the spread of communicable disease from one state, territory, or possession to another.

Under these authorities, FDA has developed a comprehensive seafood regulatory program, which contains several elements. It is an integrated program because it must, by necessity, involve other agencies, as well as state and local governments. The U.S. coastline is too vast and the seafood industry too large and diverse for any single agency to attempt to regulate seafood safety and quality alone.

Domestic Activity

Domestically, FDA has a program for inspecting seafood processors, shippers, packers/repackers, labelers/relabelers, and warehouses. Nationwide, there are about 4,000 such establishments, or roughly 6 percent of the approximately 60,000 food-related establishments in FDA's inspection inventory. About 1,000 to 1,400 of the 4,000 seafood establishments are inspected each year to verify compliance with good manufacturing practices and other applicable regulations. These figures include some inspections performed by states under contract to FDA.

Each year, FDA analyzes, or tests about 2,000 domestic seafood samples for decomposition, microbiological contaminants, parasites, natural toxins, chemical contaminants, and other potential problems. These 2,000 samples undergo a total of between 10,000 - 20,000 individual analyses to determine whether any of these problems are present.

The Agency currently has 19 field laboratories throughout the U.S. with seafood analysis responsibilities. FDA's specialists have spent many years developing their skills and many of these individuals are recognized internationally as leading experts.

Inspections and analyses of product samples are targeted to suspected plant and product defects. Consequently, inspectional and analytical results usually exaggerate the violation rates and true magnitude of problems/defects in an industry and its products.

For seafood, the violation rate of these samples varies from year to year, ranging from about 12 to 30 percent over the last three years. As I just indicated, however, these percentages should not be construed to mean that 12-30 percent of all seafood is violative, but rather reflect our ability to target problems and find what we are looking for.

A substantial percentage of violations actually reflects quality problems that convey no real health risk. In addition, seafood products may be violative under the FD&C Act if they have been packed or held under conditions in which they "may" have been contaminated, even if they have not actually become so.

Much of FDA's remaining domestic seafood efforts involve cooperative working relationships with, and various forms of assistance to states, Federal agencies and other entities. For example, through the Retail Food Protection Program, FDA provides technical assistance, model code guidance, and coordination to the states and localities who, rather than any Federal agency, inspect the literally hundreds of thousands of retail outlets and restaurants selling seafood products.

FDA also collaborates with NOAA Fisheries under an interagency Memorandum of Understanding (MOU). Under this agreement, NOAA Fisheries applies FDA requirements pertaining to adulteration and misbranding to its voluntary fee-for-service inspections.

In the area of shellfish, FDA supports--through research, technical assistance and general oversight--the National Shellfish Sanitation Program (NSSP), which is operated in collaboration with states and the industry through the Interstate Shellfish Sanitation Conference (ISSC) to enhance the quality and safety of molluscan shellfish. The NSSP provides that all fresh and frozen oysters, clams and mussels intended for interstate commerce must be tagged by certified dealers and should be processed in plants meeting sanitation requirements. The NSSP also sets minimum sanitation and safety standards for growing waters. The monthly list of certified interstate shellfish shippers compiled by FDA on the basis of state-issued permits is the definitive list of interstate molluscan shellfish processing/shipping firms operating under acceptable sanitary conditions.

Import Activities

FDA regulates imported seafood by:

- examining and sampling products on the wharf;
- analyzing the samples in the laboratory;
- automatically detaining products with a history of problems unless accompanied by an acceptable certificate of analysis; and,
- establishing and maintaining MOUs with foreign governments to improve shellfish sanitation at the point of origin.

Approximately 167,000 formal entries of seafood products are imported into the U.S. annually. FDA conducts about 4,500 wharf exams per year on seafood entries. A wharf exam occurs when an inspector examines a shipment, becomes satisfied that a sample does not need to be collected, and releases the shipment.

In addition to these wharf exams, FDA collects samples when the inspector sees something suspicious or in response to surveillance assignments or import alerts from FDA headquarters about products from certain producers or countries that may be violative. About 4,500 - 5,300 imported seafood samples are collected and analyzed each year. In recent years, FDA has targeted seafood samples correctly from 35-50 percent of the time (i.e., our import samples have been violative from 35-50 percent of the time), with most detained for biological contamination (e.g., salmonella species in imported shrimp).

Again, these results should not be construed to mean that 35-50 percent of imported seafood is violative. Moreover, a violation need not involve a potential safety problem. Violations may be relatively minor, such as the use of print that is too small on the label. Violations of this nature usually result in warnings that future shipments must be corrected. More serious violations, such as the presence of excessive mercury in swordfish or an attempt to import decomposed conchmeat, result in detention of the product.

FDA will automatically detain an imported seafood product if that product has a history of violation and there is no reason to believe the situation has changed. For example, canned seafood products from certain countries have been automatically detained because the manufacturers have not filed the required processing information with FDA to demonstrate that these low-acid canned foods do not pose a hazard of botulism to the consumer. Any product that is automatically detained cannot enter the U.S. unless the importer proves that the product is free of the problem or until a reconditioning plan acceptable to FDA is proposed and carried out.

FDA negotiates MOUs and other agreements with foreign governments to help assure that seafood products exported to the U.S. from these countries meet our standards. Currently, there are shellfish MOUs with Canada, Japan, Korea, Iceland, Mexico, England, New Zealand, Australia, and Chile. (England, and Mexico are not currently shipping because their programs do not meet the conditions of the MOUs).

To maintain the MOU, the country must demonstrate that its law, rules, or regulations are equivalent to the NSSP Manual of Operations. Also, the foreign government must have the trained personnel, laboratory facilities, and other resources necessary to control its export shellfish industry. These foreign shellfish are then subject to the same procedures (e.g., certification number tagging and listing in the Interstate Certified Shellfish Shippers List) as are domestic interstate shippers. FDA shellfish specialists periodically visit these countries to evaluate their programs and assure that their sanitary controls are adequate and up to date.

Research Activities

FDA has an active regulatory-related research program to address the public health concerns associated with seafood. This work is conducted through scientific divisions in Washington, D.C., Davisville, RI, and Dauphin Island, AL. Additionally, FDA's Seafood Products Research Center in Seattle, as well as its district laboratories located around the nation and in Puerto Rico, conduct seafood research for the Agency. A small amount of extramural research is conducted by contract with academia, foundations, and states. FDA's research groups use suggestions from the Agency's nationwide field force in determining the overall seafood research priorities.

Major efforts are devoted to identifying naturally occurring toxins and developing analytical methods for them as well as to developing methods to identify chemical indications of decomposition and to detecting and quantifying biological and chemical contaminants in seafood. A wide range of projects is under way in these areas that relate both to finfish and shellfish. Since fish are a highly perishable commodity, analytical time must be as short as possible.

FDA is a recognized world leader in the application of new technologies such as the development of rapid, specific test systems using recombinant DNA and monoclonal antibodies. In the microbiological area, FDA uses these technologies to develop and apply tests that will selectively detect only organisms that pose, or at least suggest, a threat to human health. FDA has two patents pending on genetic tools to detect pathogenic bacteria, and shares technologies with CDC and foreign government health agencies.

Another important area of research in which genetics may play a key role is the development of indicators of water quality. FDA and CDC are jointly researching the possible use of methods to "amplify," or increase the number of copies of viral genetic material--a technological byproduct of AIDS research. If viruses that can infect shellfish could be detected directly (they presently cannot be cultured outside the living human), a high degree of safety assurance could be given harvested raw shellfish tested in this manner. "Amplification" of the viral genetic material would make the viruses detectable with gene probes.

FDA has also initiated a comprehensive field study of the relationships between indicators and water quality parameters in response to a request from the state of Texas. The Agency is also working with the ISSC and other groups to design field and laboratory research to address questions in this area.

FDA is also focusing on aquaculture and the particular problems associated with pond-reared fish and other aquatic species, such as the need for drugs that can be used safely and effectively. FDA's broad scientific base is especially valuable here. The Agency's Center for Veterinary Medicine is uniquely qualified to support extramural research in this area, including comparative drug metabolism and bioavailability studies in various fish species with drugs that demonstrate potential for disease treatment and control. Another aspect of FDA's aquaculture research has already resolved the question of whether potentially harmful aflatoxins might accumulate in the edible muscle of pond-reared catfish that consume moldy fishfeed, a significant grounds for concern had it been true.

FDA also has a research MOU with NOAA Fisheries to coordinate relevant research activities conducted or supported by each agency. Research under the MOU now involves 25 projects.

Education

FDA has a number of activities devoted to education, training, and scientific and information exchanges on seafood and seafood safety. Since 1984, the Agency has published from one to three articles per year on some aspect of seafood safety in its monthly magazine, the FDA Consumer. In addition, seafood is also included as a topic in articles, reports, press releases, and advice on food safety subjects issued by FDA. FDA also has a nationwide network of Consumer Affairs Officers who work closely with local media, health professional, and community-based organizations, appear on local television and radio programs, answer questions from consumers, give lectures, provide brochures, and write articles.

FDA scientific staff and regulatory personnel make presentations at scientific meetings and publish research results in the scientific literature. FDA staff present seminars in foreign countries with emphasis on practices that would lead to reduced detention rates of products from those countries.

FDA frequently offers "hands-on" training courses in organoleptic, or sensory analysis of seafood. Following the Exxon Valdez oil spill in Alaska, for example, FDA scientists conducted a series of organoleptic analysis training sessions for inspectional personnel from the state, NOAA Fisheries, boat owners, and processing plant quality assurance staffs. Organoleptic analysis has been an important screening technique for keeping fish contaminated with oil off the market.

Another area of training is in low-acid and acidified canned foods. A large percentage of the seafood consumed in this country falls within the definition of this type of food, including canned tuna. The regulations governing these foods require that the supervisors of industry personnel in specified critical areas satisfactorily complete FDA approved training. Additionally, FDA investigators receive specialized training in inspection techniques including Hazard Analysis Critical Control Point (HACCP) training for low-acid and acidified canned food inspections. HACCP will be addressed in greater detail later in this statement.

TRENDS AND CONCERNS

Like the industry it regulates, FDA's integrated seafood safety program is both diverse and complex; yet it also must be responsive to new developments and trends. Indeed, there are a number of significant challenges for the future. I will attempt to summarize these challenges and to describe the directions that we believe our program should take so that the American people can continue to eat seafood with confidence.

First, the clear potential for industry growth, both in terms of species and quantity of fish that can be consumed, presents FDA with a number of challenges across the regulatory spectrum. These include developing and maintaining a comprehensive information base about possible toxins and contaminants to inspecting and sampling of a potentially larger volume and variety of seafood in interstate commerce.

The advances in seafood technology, characterized by aquaculture and engineered, mechanically deboned seafood known as surimi, raise a host of new issues for us. Aquaculture is still in its infancy. Projections for growth of this industry through the year 2010 are staggering and the Agency must be adequately prepared. For example, many of the drugs that could be used in the production of pond and pen-raised fish have been utilized for many years in land husbandry; however, more needs to be known about drug residues that may result from their use in fish. These developments require new research.

Concerns over the consequences of environmental pollution and the risks from other sources that have been described in this testimony are causing people to ask whether a more intensive Federal inspectional program is needed in order to maintain seafood safety and continued public confidence in seafood products. FDA's inspection program involves approximately one-fourth of all domestic processing establishments annually and NOAA Fisheries' voluntary inspection program helps provide some additional coverage. The Administration is undecided about whether more domestic inspections ought to be conducted, and whether more imports should be sampled and analyzed. No final determination has been made on this issue. FDA's sampling of imported seafood involves only a small percentage of the increasing amount that is being imported.

A related concern is the quality of data available on seafood-related illnesses. The acknowledged underreporting of the illnesses that are occurring from seafood (and from other foods) can only add to the concern that there are too many unknowns, requiring more regulatory "hands-on" from harvesting to market.

One area in which we know there are problems is the safety of molluscan shellfish, especially when eaten raw or partially cooked. Polluted water in shellfish growing areas is a primary cause, and bootleggers are known to harvest from these areas in spite of NSSP efforts. The bulk of the shellfish producing states are making every effort to ensure that only safe shellfish are harvested from their waters and they deserve credit for a commendable job.

In the area of research, FDA must, among other things, continue to develop analytical methods and obtain data that are currently lacking to establish additional regulatory limits for contaminants.

FUTURE CHALLENGES AND ALTERNATIVES

We will consider the following challenges and alternatives in deciding upon any additional methods for insuring seafood quality and safety. As this discussion will demonstrate, it is critical that we continue to build upon the multiagency, integrated program of Federal-state relationships that has been painstakingly developed over the years for this very purpose.

1. Processing Plants

The inspection of processors is an area in which an integrated approach involving the States, FDA, and NOAA Fisheries could lead to a significant enhancement in the frequency of inspections. We are currently exploring whether and how we could pool our resources with the states and NOAA Fisheries through a division of labor for surveillance-type inspections while FDA would provide laboratory analytical support, "for cause" followup inspections and general audit-type inspections. The frequency of surveillance inspections would depend on the type of operation and previous inspectional history. The division of labor could be based on degree of difficulty and traditional roles (e.g., difficult inspections involving low-acid canned foods would logically remain a Federal responsibility.)

Both FDA and NOAA Fisheries have a strong interest in the use of the "HACCP" system of industry safety control practices to the seafood industry, and any joint FDA-NOAA Fisheries endeavor would work toward that goal. HACCP stands for Hazard Analysis Critical Control Point and was first utilized by FDA in the early 1970's to control microbiological hazards in the mushroom canning industry. After considerable refinement, FDA also applied HACCP to various other food products, particularly low-acid canned foods.

HACCP involves the identification and subsequent self-monitoring of the "critical control points" in the handling and processing of a food that require the greatest attention because they involve the greatest risk if not performed properly. For low-acid canned foods, the identification of the critical control points and appropriate monitoring systems to be carried out by the industry was a cooperative effort involving both industry and the government.

HACCP also involves training key people involved in food processing as well as ensuring that plant inspections place major emphasis upon review of the firm's own monitoring results. For the seafood industry as a whole, including ships, a transition to HACCP systems would be a substantial undertaking, but would be a vital step toward making a more comprehensive, manageable Federal seafood safety program possible. It would also continue to place primary responsibility for establishing and maintaining quality assurance for seafood with the industry that profits from it, as is the case with other industries that FDA regulates. FDA Good Manufacturing Practices regulations could form the basis for the industry's HACCP plans. NOAA Fisheries has already been working with the seafood industry on the HACCP plan concept and we certainly commend that effort.

Ideally, HACCP plans and self-monitoring would be phased in as an industry-wide practice. Such a system could be developed for a "mark" to identify seafood products from processors who have passed inspection. Also, an inventory of processors through a registration system would be essential to effectively manage an enhanced inspection program.
While increasing the frequency of domestic inspections of processors may be desirable, it is worth pointing out that a "continuous," visual-type inspection program would be costly and probably would not provide commensurate safety benefits. We understand that the Food Safety and Inspection Service of the Department of Agriculture, the agency responsible for inspecting meat and poultry, uses about 9,000 staff years and 7,000 inspectors at a cost of approximately $400 million.

A continuous, visual-type program for seafood would be effective for monitoring sanitation and quality (although

GMP-based HACCP inspections would be sufficient for this purpose too), but, as I indicated earlier, most potential safety problems involve contaminants that require laboratory analyses to detect. With current technology, continuous, on-site inspection would not accomplish this function.

2. Imports

Although FDA has a highly directed import sampling program coupled with automatic detentions to stop chronic violators, there is still a concern over the volume of imports that do enter interstate commerce without being sampled.

We believe the MOU concept should be extended to include finfish as well as shellfish and to incorporate the HACCP concept into each MOU. Foreign governments could serve as the surveillance monitors to insure that foreign processors have, and are implementing HACCP plans, while FDA engages in audit and "for cause" inspections. FDA investigators already travel overseas to inspect a limited number of firms that export FDA-regulated products to the United States. Again, those who incorporate HACCP and pass inspections would be entitled to the use of a "mark."

As an aside, we are aware that foreign countries are increasingly requiring American exporters of seafood abroad to have U.S. Government imprimatur, in effect, relating to the quality of their products. While FDA's overriding concern will always be the protection of the public health, we are mindful of the importance of providing a "level playing field," so to speak, for both imports and exports.

3. Research and Related Matters

An aggressive and capable research component is essential to a successful seafood safety program. We are proud of the accomplishments of our scientists to date, but as I have indicated, there is much work remaining to be done, especially in the areas of maximum permissible levels for various potential contaminants, rapid detection methodology, and indicators relating to water quality.

Tolerance setting is, in essence, the product of risk assessment, which in turn requires both a toxicological and a consumption "profile." Consumption refers to data on what and how much seafood people are eating, both as a nation as a whole and by various subgroups. FDA's consumption data must be updated in order for tolerance setting to proceed much beyond its current state.

Another data system--that for seafood-related illnesses maintained by CDC--could be greatly improved by applying existing models to overcome the very real problem of underreporting. One such model involves the establishment of "sentinel surveillance" systems that have been shown to give accurate projections of disease incidence for the United States. FDA and CDC already have considerable experience with such systems for illnesses caused by the Listeria and Campylobacter bacteria. This experience could be applied to seafood-related problems and greatly enhance the accuracy of illness data that are now available.

Establishing a "sentinel surveillance" system involves selecting a representative geographic region of the country and then scrutinizing all hospital discharge records from that region for the particular diagnosis (e.g., Listeria). An individual food consumption study is performed for each positive diagnosis found. Such studies allow the identification of foods associated with the transmission of disease.

Another area where research is needed to fill gaps involves economic deception. If the industry resumes its previous growth and continues to expand into new species and technologies, the potential for deception may grow with it.

Economic deception can include overbreading and ice-glazing to increase weight, as well as species substitution in which cheaper fish are fraudulently substituted for more expensive, desirable species. FDA has been involved in research aimed at thwarting all of these, but more still needs to be done.

4. Education

FDA's education and information dissemination activities are already comprehensive, but for the future, two primary challenges emerge. The first involves providing even more information than we already do now to consumers about (a) how to select seafood wisely and handle seafoods properly after purchase, and (b) what is known about foodborne hazards and the relative levels of risk they pose. As was pointed out earlier in this statement, proper handling can eliminate many seafood-related causes of illness. Public misperceptions about foodborne hazards and relative risks can be hazardous too, especially if people avoid healthy foods out of fear and substitute less healthy foods in their place.

The second challenge that emerges involves the need for widespread training in HACCP principles if that system is ever to become a standard for the seafood industry. FDA will present three shellfish plant sanitation courses to senior state shellfish regulators and FDA specialists in the near future and will develop training manuals and information packets in conjunction with the Association of Food and Drug Officials.

CONCLUSION

This statement has presented an assessment of FDA's seafood safety program from the standpoint of the challenges that face us and the Agency's current thinking on how best to meet those challenges. A national seafood program would require an integrated, comprehensive program of surveillance from water to table that would rely on a Federal-State partnership to accomplish what neither could do alone.

The primary responsibilities of the Federal government will likely always be to conduct research, perform analyses, set standards and tolerances, and monitor or oversee the monitoring of the "constriction points," such as ports of entry and the processing plants that are interposed between water and table. It is at these points that samples can most effectively be collected for the myriad of laboratory analyses that may be needed.

Seafood products may be subjected to numerous abuses between water and table. Fortunately, these abuses do not occur very often. But the potential definitely exists, and it may well be growing. Through farsighted management of our program, we will continue to make every reasonable effort to prepare for new technologies, respond to trends, and solve existing and potential problems in order to ensure that we are never overcome by them. This concludes my prepared testimony. I will be glad to answer any questions you may have.

TESTIMONY OF
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U.S. DEPARTMENT OF COMMERCE

BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE

OCTOBER 24, 1989

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to appear before you today on behalf of the Administrator, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce (USDC), to discuss seafood inspection. Seafood safety is an important issue affecting fisheries, consumers, and the fishing industry.

First, let me congratulate you and the Committee for considering this important issue of how best to ensure the safety of seafood available for public consumption. We also appreciate the efforts of the public and industry advocates in raising this issue. The Administration recognizes the importance of seafood safety. At this time however, we cannot support enactment of specific legislation for seafood inspection. Whether or not to establish an expanded inspection program, or which agency should administer such an expanded program if the Congress were to establish one, is an issue currently under review by the Administration. In my testimony I will review one of the alternatives being considered within the Administration.

Consumer awareness of and interest in the health benefits and nutritional value of seafood in recent years have fueled increased consumption. This increase, however, has been accompanied by growing complaints of economic fraud, including mislabeling and other fraudulent practices, inconsistent and often poor quality and even unwholesome product. These complaints apply both to domestic and imported products. They come from consumer advocates, fishermen and others within the industry, and from retailers and other users of seafood. Questions also are beginning to be raised by foreign officials and buyers as to the wholesomeness of U.S. seafood and the conditions under which they are harvested and processed. The media has focused international attention on the serious problems of polluted beaches and estuaries, ocean dumping, oil spills, chemical contaminants, parasites, unsafe shellfish growing waters, and naturally-occurring toxins both in the United States and abroad. Consequently, there is growing public concern about the safety and acceptability of our seafood production and supplies.

Any decision about what, if any, additional Federal intervention is appropriate, should be based on the issues of public safety, consumer confidence, and a domestic seafood industry operating in highly competitive domestic and world markets. These markets are competitive not only in the context of other suppliers of seafood, but also with respect to other animal protein products such as beef and chicken.

In the inspection of plants and in the assessment of baseline acceptability of fishery products, the Food and Drug Administration (FDA) and NOAA goals are the same: to ensure that safe, wholesome, and properly labeled fishery products are sold in interstate commerce. FDA operates a compliance program to ensure that seafoods are in compliance with the requirements of the Federal Food, Drug and Cosmetic Act of 1938, as amended, and other legislative acts. Additionally, that Agency participates in cooperation with States and industry associations in conducting specific seafood surveillance programs such as the National Shellfish Sanitation Program and the Salmon Control Plan.

FDA periodically samples imported fishery products, along with numerous other food products, at points of entry into the United States. Its other major activities relative to fishery products are the review of product and process registrations for domestic and imported low-acid canned foods, food additive approval and review, and periodic evaluation of processing facilities engaged in interstate commerce.

NOAA operates a voluntary Fishery Product Inspection Program that is voluntary in the sense that a processor may choose to participate or not. Once a processor participates, the Program is mandatory for a stated period of time, and a contract is signed to that effect. In our program, we enforce the FDA requirements as well as NOAA regulations. Our Program is operated on a fee-for-service basis and provides in-plant sanitation and process control evaluations and product evaluation and grading services for affixing Packed Under Federal Inspection (PUFI) and U.S. Grade marks to complying product. Lot inspections of product in warehouses, etc., are often requested and performed on imported, domestically marketed, and exported products. We also provide consultative services in the areas of plant sanitation, product reconditioning, specification development and review, labeling review and guidance, as well as analytical services in chemical and biological risk areas.

During 1988 our inspection services were used by more than 400 brokers in import, domestic, and export trade, State and Federal agencies, and, on a yearly average, 132 processors (approximately 7 percent of total number of fishery products processors in the United States). The Program inspected a total of 495.5 million pounds of fishery products in 1988. One could say then that approximately 11 percent of the product consumed in the United States was subjected to some degree of inspection under this USDC Program and approximately 9 percent of edible U.S. exported fishery products were also inspected.

The Program augments its total staff of approximately 160 full-time, part-time, and temporary personnel, through the use of State/Federal cooperative agreements and cross-utilization agreements. Under these agreements inspectors are called upon to perform site-specific inspection services. We accept training responsibilities, cross-license these inspectors, and reimburse the State or Federal agency for the cost of providing personnel from the fees collected for the USDC services provided.

Such agreements with the States are typically used to service sporadic or low level inspection needs in the areas where NOAA inspection personnel are not routinely stationed. The advantage of such agreements is that they allow for a cost effective means of providing identified inspection activities through the inspectional capabilities of other State and Federal agencies, provide focused training to address specific inspectional needs in an area, upgrade the talents of the local inspection staff, and does not unnecessarily increase the staffing requirements of the NOAA program.

For example, under the current State/Federal cooperative agreements, NOAA has trained and can utilize the services of 100 cross-licensed State inspectors. The activities of these cross-licensed State inspectors, performed on the behalf of the USDC inspection program, range from sanitation inspections of processing facilities in the New York metropolitan area, through lot inspections of products in remote locations of Alaska, to statistically-based integrated quality assurance activities in sophisticated surimi and analog product processing facilities in Minnesota. NOAA is particularly well suited to this role of training State inspectors and integrating such inspectional activities in State/Federal programs because of its mission and scientific and technical expertise in the areas of harvesting, processing, storing, and marketing of fish and fishery products.

The degree of involvement of the State agency is dependent on the inspection needs in the area, the location and availability of USDC inspectors, the availability of State inspection personnel in the area of need, and the desire of the appropriate State agency to become involved in additional inspection activities. Because of these factors, State inspection activities on the behalf of USDC may range from sporadic, as is the case in the State of Florida, to virtually all USDC-related inspection activities performed by the State, as is the case in the State of New York.

Interest in cooperative inspection activities continues to increase. An agreement is currently under development with the State of Washington which will further add to our ability to provide timely, cost-effective inspection services to the benefit of the industry and consumers.

The National Marine Fisheries Service (NMFS), through its product seafood research programs, provides analytical and related services and information on product safety, quality and identity impediments to the full utilization of the fishery resources.

Safety research includes activities that address a continuing concern regarding the impact of environmentally and process-induced contamination of seafood on consumers and the fishing industry. NMFS's quality research efforts are directed to improving the overall quality of U.S. seafood marketed domestically and internationally. Utilization Research Programs dealing with fishery product quality and safety are located in these NMFS facilities: Gloucester, MA; Charleston, SC; Pascagoula, MS; Seattle, WA; and Kodiak AK. Over $6 million in fishery product safety and quality research is conducted through NMFS Laboratories and extramural funding programs.

NOAA's Status and Trends Program develops information on environmental quality conditions in U.S. coastal waters through monitoring levels of contaminants in selected finfish and shellfish at over 200 sites. Such information is used to focus fishery product quality and safety related research to determine the public health significance of contaminants in fish and shellfish found in U.S. waters.

In addition to cooperative agreements on inspection and research, FDA and NOAA also developed a Memorandum Of Understanding (MOU) in 1986 to conduct joint enforcement actions against individuals who harvest molluscan shellfish from closed waters. Working jointly with State and Federal enforcement officials, NOAA and FDA have successfully used the Lacey Act, which we administer, to prosecute individuals involved in bootlegging networks on the East and Gulf Coasts.

Bootlegging of molluscan shellfish from closed waters is a blatant disregard for the health and safety of others which is universally condemned. There are other problems associated with the shellfish industry which are much more complex. Solution of these problems will continue to require the best cooperative efforts of industry and government. Through the Interstate Shellfish Sanitation Conference, industry representatives, the academic community, officials from both shipping and receiving States, and officials from FDA and NOAA are dealing with issues such as test methods for indicators of human bacterial and viral diseases, depuration practices which will result in safe shellfish for raw consumption, and proper handling practices to result in wholesome, good quality shellfish at destination.

Under the Research MOU between FDA and NOAA, scientists from the two agencies are developing a long-term research plan to address the most critical seafood safety issues. Among the highest priority areas identified are risk assessment and management of contaminants in seafood products, Listeria, and molluscan shellfish.

Research to identify contaminants and their respective levels in the waters in the end fishery products consumed by the public, is only one part of the puzzle. We must also know how these compounds are likely to affect the consumer at various levels over time. Consumption data are also needed in order to determine how much of a certain species or product will be consumed over the period of time in which the contaminant or toxic product will act.

NOAA is also currently carrying out research on Listeria. The overall objective of the research is to increase the safety and marketability of ready-to-eat fishery products by identifying the critical control points in the processing of the products in relation to the survival and growth of Listeria monocytogenes, and to develop process parameters at these points that will increase the safety of the products. The factors that contribute to the virulence of Listeria monocytogenes and the genetic mechanisms mediating virulence are being studied. NOAA is also currently funding a study, in collaboration with FDA and the molluscan shellfish industry, to develop better indicator organisms to assess the safety of shellfish growing waters.

Finally, NOAA has been working with the State of Alaska and the FDA to implement a quality assurance program for seafood that may be impacted by the Prince William Sound oil spill. These activities include using fisheries management authority of NOAA and the State of Alaska to close areas to fishing where visual inspection coupled with appropriate, extensive laboratory support is being used to determine the possible presence of petroleum hydrocarbon residues using sophisticated analytical methods developed by our fisheries research center in Seattle, and a program of fish and fish product inspection to segregate unacceptable products. Our collective efforts have been successful in preventing oil tainted products from reaching the marketplace.

To place the overall situation in perspective, we believe the U.S. consumer is not facing a national public health crisis. Nevertheless, certain fisheries may warrant stricter regulation to prevent practices such as the marketing of shellfish harvested commercially and recreationally from polluted waters, and to address problems of scrombroid poisoning and ciguatera. These problems, account for almost 90 percent of the public health outbreaks with confirmed etiologies as reported to the Center for Disease Control for the period 1983-87.

Scombrotoxin is a by-product of the naturally-occurring amino acid, histidine, which is present at relatively high levels in the flesh of species such as tuna, mackerel, bonito and mahi-mahi. It generally develops on the harvesting vessel due to the mishandling of fish. It is important to note that the toxin may build up to levels sufficient to cause illness before other decomposition products, recognizable by unpleasant odor, are present to warn a consumer of the potential danger. Scombroid poisoning can cause severe discomfort but is more often mild in nature, rarely lasting for more than a day. It produces symptoms sometimes mistaken for allergic reactions, such as skin rashes, flushing, and itching sensations.

Ciguatoxin is believed to originate in certain microscopic algae which grow on reef structures in tropical waters. It accumulates, under generally unpredictable conditions, in the flesh of commercially important fishes which live and feed in the vicinity of the reefs. Some snappers, groupers and barracudas are among the species that have been identified as capable of carrying the toxin. Ciguatoxic fish are indistinguishable from non-toxic fish; they appear healthy and immune to the toxin they carry. As seafood, they have no characteristic odor or taste to alert a consumer of potential danger. Ciguatoxin itself is heat stable and is not removed or rendered harmless by cooking. The illness it causes, ciguatera, is manifested by disturbances in the digestive, cardiovascular, and neurological systems. It is often debilitating but rarely fatal.

In the case of both molluscan shellfish and ciguatoxic illnesses, these illnesses are attributed to contamination from either microbiological or chemical agents in the individual fish or shellfish. These contaminations are directly related to the waters from which the animal comes and can thus be classified as environmentally-induced product safety hazards. These problems plus scromboid poisoning can be addressed by tightening harvesting requirements involving a combination of actions - proper classification of molluscan shellfish growing waters and harvest controls, identification of known ciguatoxic reefs, and stronger enforcement of harvesting regulations and procedures.

The 1,100-member National Fisheries Institute, the largest U.S. seafood industry trade association, conducted a survey in 1985 of its members (fishermen, fish processors, importers, and exporters) to assess their perceptions of the consumer protection issues relating to fishery products and the belief that an improved Federal inspection system was needed. Respondents believed only molluscan shellfish justified broad-spread safety-related concerns. However, they expressed widespread concern relating to economic fraud, including added water, species substitution, and mislabeling of products; and the belief that an improved Federal inspection system was needed.

Results of a two-year General Accounting Office (GAO) study on seafood inspection issues were released in August 1988. While pinpointing several shortcomings in the current Federal/State inspection system, GAO concluded that seafood does not need a continuous ante- and postmortem inspection system similar to current Federal meat and poultry inspection. Further, GAO supported NOAA's ongoing study to develop an improved system of inspection and certification of seafood products tailored to the unique needs and problems of the seafood industry. Congress appropriated funds for the study in fiscal years 1987 - 1989. The study will be completed in December 1990.

A review of the success of major fish-producing countries in capturing and maintaining significant shares of world markets, including their own, reveals several similarities in the manner in which the safety and quality of their seafood are addressed. Some of the similarities are:

- Commitment, clear leadership and effective organization of authorities and responsibilities to ensure safety, quality and proper labeling as a matter of Government policy, whether for domestic consumption or export.
- Product control systems to address safety, quality and proper labeling from the point of harvest to the point of sale, including adequate monitoring of both chemical and microbiological contaminants.
- Government and industry cooperation to establish technical product and processing standards that are used to achieve industry-wide uniformity.
- Mandatory controls and inspection requirements on the domestic harvesting, processing, and distribution facilities and products to address sanitation and wholesomeness problems.
- Mandatory standards applied equally to the facilities and products of importing countries to maintain uniform consumer protection and to ensure that domestic markets are not inundated with questionable product that would compete with domestic production.

It should be clear that if the United States is to maintain its position as a leading producer of and market for fish and seafood products, our products must meet similar levels of assurance of product safety, quality, and labeling.

Fish and shellfish in the United States are handled and processed by many entrepreneurs, some with very small operations, whose equipment and awareness of good storage and processing techniques vary from rudimentary to sophisticated. The difficulty of providing plant inspection for the hundreds of independent fish processing plants is complicated by the fact that 128,000 vessels harvest the fish that go to the processors and that the seasons of production vary. Compounding this is the fact that 63 percent of the seafood consumed in the United States is imported from over 120 countries with varying degrees of seafood inspection competence. Finally, a significant amount of fresh seafood doesn't move in interstate commerce; necessitating a strong and continuing State involvement.

We believe there are a variety of issues that need to be addressed in deciding whether to implement a new seafood inspection program, including: 1) potential changes in seafood inspection philosophy and program design; 2) the inadequacy of present regulatory and enforcement authorities, 3) the appropriate Federal and State roles; and 4) program costs and source of funding.

1) Potential Changes in Seafood Inspection Philosophy and Program Design

One option the Administration will consider is a seafood inspection system based on problem prevention backed by strong enforcement. This approach has been adopted by leading seafood-producing countries such as Canada. Such a system design would include:

- Developing and implementing a seafood inspection program based upon Hazards Analysis Critical Control Points (HACCP) principles, tailored to the needs of particular fisheries, that addresses issues of plant and vessel sanitation, product safety, and economic fraud.
- Expanded monitoring of fishery products for both chemical and microbiological contaminants.
- Prohibiting or restricting through fisheries management plans, harvesting fish from certain areas to prevent processing and marketing unsafe fishery products.
- Developing and adopting mandatory minimum sanitation standards for harvesting, processing, transporting and storage of fishery products.
- Developing or amending product-related fishery product standards consistent with international standards pertaining to quantity, minimum quality, packaging and labeling.

2) Adequacy of Present Regulatory and Enforcement Authorities

The Administration is reviewing whether legislative authority is needed for:

- Creating a mandatory plant and vessel registration and certification system.
- Granting access to records pertinent to HACCP principles.
- Granting product detention authority to inspectors for domestic products.
- Imposing stricter civil and criminal penalties for specified violations of prohibited acts.
- Establishing and monitoring technical arrangements with appropriate agencies of foreign countries for mutual acceptance of inspection systems or analytical results.

3) Appropriate Federal/State Responsibilities

One alternative under consideration by the Administration is a new inspection system based upon:

- Continuing the joint responsibility of NOAA and FDA for seafood inspection and enforcement, but establishing NOAA as the lead Federal agency for day-to-day inspections.
- Maintaining current responsibility within FDA for health standards and having FDA oversee NOAA Fisheries inspection and enforcement activities with particular emphasis on public health issues.
- Fully cooperating, on a partnership basis, with those States and foreign countries that have in place a program fully equivalent to Federal requirements.

4) Program Costs/Funding

In the current fiscal climate, the Administration believes that funding for any increased Federal seafood inspection activities should be paid for by the industry through user fees.

The authority of the Secretary of Commerce under this approach would complement the authority of the Secretary of Health and Human Services. There are several reasons why such an approach is desirable.

The Department of Commerce has demonstrated an ability to combine in one agency the functions of promoting and regulating the fishing industry, particularly the harvesting segment of that industry. For example, it regulates the industry under the Lacey Act, the Marine Mammal Protection Act, and the Magnuson Fishery Conservation and Management Act (Magnuson Act), while promoting the industry under the Fish and Wildlife Act, the National Sea

Grant College Program Act, Title XI of the Merchant Marine Act, and the Fishermen's Protective Act. The functions of the Department of Agriculture in promoting the red meat and poultry industries have not affected the credibility of its continuous inspection program for these industries.

The Department of Commerce has considerable fisheries expertise and a long history of involvement in inspection of fishery products under the voluntary program established by the Agricultural Marketing Act. The Department conducts applied research into the utilization of fishery products, and it has extensive knowledge of the industry. These characteristics make the Department a viable candidate to assume an expanded role, in coordination with FDA, in the inspection and regulation of fishery products.

Since this approach would permit the FDA to continue its present role of risk assessment establishing tolerances where appropriate with respect to seafood product safety and verification, but in closer cooperation with the Secretary of Commerce, it would not be necessary to replicate the continuous inspection system of the Department of Agriculture to enhance public confidence in the quality and wholesomeness of fish.

Mr. Chairman, we realize you are in the process of developing legislation to establish a mandatory seafood inspection program. We strongly feel that such a program must address not only the safety and wholesomeness of processing activities but also the harvesting of seafood, where product safety and sanitation problems frequently occur. We believe that legislative changes in seafood inspection authority should address problems of sanitation, product safety, and economic fraud at all levels of seafood production and distribution. This approach therefore would mandate coverage from the growing waters to the marketplace. It would be much more effective and cost efficient to deal with problems related to seafood safety at-sea, before violative material is processed and enters distribution channels.

We believe any regulation of harvest areas for public health purposes should be carried out under existing fisheries management authority. Under the Magnuson Act, NOAA routinely opens and closes harvest areas tied to conservation and management objectives. Most recently, NOAA took emergency action under the Federal Surf Clam Fishery Management Plan to prohibit harvests of surf clams in an area of Georges Bank off New England. This action was taken because of levels of Paralytic Shellfish Poison in surf clams that exceeded recognized safety standards. As I stated, authority to regulate at sea to address product safety and vessel sanitation concerns is needed and should be carried out in concert with current fisheries management activities.

To implement a comprehensive mandatory inspection program, I believe a full partnership with the States will be required.

Currently, the States are providing varying degrees of inspection coverage in the seafood area. Authority would be needed to delegate inspection activities to States with programs meeting Federal standards. We must build a partnership with the States. By building upon existing State infrastructures we can minimize the need for potentially redundant Federal bureaucracies where State programs can demonstrate their ability to apply Federal standards. If a State cannot or chooses not to administer Federal standards, then a direct Federal presence would be required.

As we stated, the Administration does not support enactment of any new seafood inspection legislation at this time. However, we look forward to working with the Congress to address this important national issue, the safety and quality of our seafood.

TESTIMONY OF ELLEN HAAS
EXECUTIVE DIRECTOR
PUBLIC VOICE FOR FOOD AND HEALTH POLICY
BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
ON SEAFOOD SAFETY AND INSPECTION

October 24, 1989

Chairman Leahy, members of the Committee, my name is Ellen Haas. I am the Executive Director of Public Voice for Food and Health Policy, a national non-profit consumer research, education and advocacy organization working on issues of health, nutrition and food safety.

I appreciate the opportunity to appear before you today to document the serious health risks to consumers in our seafood supply and the inadequacy of current federal and state inspection programs which leave consumers vulnerable to acute illnesses, sometimes death, as well as to risk of cancer.

Since 1983, with our publication of "A Marketbasket of Food Hazards: Critical Gaps in Government Protection," Public Voice has advocated increased mandatory federal monitoring for fish safety as a means of reducing toxic contamination of fish and shellfish. We believe these foods present unnecessary, and too frequently, harmful risks to unsuspecting consumers.

Since that time, we have organized a nation-wide coalition of 35 consumer, health, and environmental groups calling for a comprehensive mandatory federal seafood inspection program. The list of these groups is included in my remarks submitted to the Subcommittee.

Mr. Chairman, we applaud your concern about the current programs monitoring seafood safety and for convening today's hearing. We further commend you, Mr. Chairman, and other members of the Committee for introducing legislation calling for the establishment of a mandatory federal seafood inspection program. These proposals address many of the concerns Public Voice has expressed about the current lack of protections for seafood consumers. We believe that this is an issue whose time has come and we look forward to working with you throughout this critical process.

The Surgeon General and the National Academy of Sciences have warned that the American diet is too high in fat, increasing the risk of heart disease, stroke, and certain cancers. These reports build on previous recommendations from the American Heart Association, American Cancer Society, and the National Institutes of Health. Even the US Department of Agriculture and the Department of Health and Human Services issued Dietary Guidelines for Americans in 1980 that called for diets lower in fat.

Americans have heeded this advice and turned increasingly to fish and shellfish for a low-fat alternative source of protein in their diets. Annual consumption of seafood in the United States increased by over 20% between 1980-1987 and is now close to 4 billion pounds.

Yet the sad irony of this healthful promise to consumers is that **seafood is the only flesh food in this country not subject to a comprehensive, mandatory federal inspection program.**

Recently, questions about the safety of seafood have been receiving increasing attention. In January, a special committee of the National Academy of Sciences Food and Nutrition Board began a two-year investigation into the health effects on the consumer from microbial and chemical contamination of fish.

And last year, public concern over fish safety showed up in the marketplace when, after a steady eight-year increase, seafood consumption went down by two percent. The change in public attitudes toward fish are documented in the results of a recently-released Harris public opinion poll conducted in November 1988 for Prevention Magazine. While the number of people buying low-fat or low-cholesterol foods rose nine percentage points from the year before, individuals reporting they try to eat fish twice a week dropped six percentage points since 1987.

The Risks of Acute Illness from Seafood

Seafood has certain characteristics which increase its potential to endanger human health. The risk of acute illness from bacteria and parasites is greater in fish and shellfish, which, unlike most meat and poultry, is generally harvested from uncontrolled environments. The waters from which fish are taken may be polluted with sewage, industrial chemicals, or pesticides.

In addition, certain types of seafood, such as shellfish, actually concentrate contaminants in their tissue. Even when refrigerated, fish and shellfish usually deteriorate quickly. And some seafood is commonly eaten raw.

It is estimated that thousands of Americans become ill each year from eating contaminated fish and shellfish. (See Chart A for a list detailing the most prominent microbiological hazards.) Disease-causing agents, like ciguatoxin and vibrio cholera bacteria, cause symptoms such as nausea, diarrhea, vomiting, fever and abdominal cramps, among other effects.

A summary of foodborne disease surveillance from the Centers for Disease Control (CDC) covering the 5-year period 1982-1986 reported 349 foodborne outbreaks of disease with known sources traced to animal muscle protein or flesh foods. According to the CDC figures, the total number of reported outbreaks traced to fish and shellfish actually exceeded the total reported outbreaks traced to beef and poultry combined. Seafood accounted for 56% of the outbreaks, beef represented 12%, and poultry 12% of the total outbreaks with a known source.

These figures take on added significance because we eat more than four times as much beef and three times as much poultry as we do seafood.

When examined together with USDA consumption data for each of these food groups for the same period, the data shows that the relative risk of illness outbreaks for seafood compared to other meats is very high. **In fact, the risk of a food poisoning outbreak from eating seafood is actually 25 times greater from seafood than it is for beef, 16 times greater than for poultry, and 16 times greater than for pork.** (See Chart B.)

The Food and Drug Administration prefers to use figures on individual "cases" of food poisoning rather than "outbreaks," which involve two or more people. However, even when using individual cases as a means of comparison, the results are still disturbing. CDC figures recently cited by FDA in the number of cases of disease during the period 1973-1987 indicate that seafood is three times as likely to cause illness as beef and one-and-a-half times as likely as poultry.

Quantifying the precise extent of illnesses proves impossible, however, as no effective nationwide system for collecting foodborne illness statistics exists. Underreporting in the case of fish and shellfish-related incidents is further compounded by the fact that many of the illnesses are gastrointestinal problems resembling a serious bout with the flu and may never come to the attention of health officials. CDC estimates that the outbreaks they document represent only between 1 percent and 5 percent of the actual number of outbreaks.

Frequently, representatives of government and industry say that 40 percent of reported seafood illnesses come from 9 states. This in large part can be explained by our poor reporting system. The quality of the data on foodborne illness depends on the priority given to foodborne disease surveillance by state and local health departments. Many states simply do not have the resources to monitor disease outbreaks. It is not surprising, for example, that New York State has one of the nation's best illness data collection systems and reports a large number of illnesses. But one would have to expect that its neighboring states would have similar illness rates proportional to their populations.

At FDA's December 16, 1988, "National Meeting on Cooked/Processed Seafood", Dr. John E. Kvenberg of FDA's Division of Microbiology presented disturbing results of FDA's 1988 microbial testing of processed seafood. Because processed seafood will usually not be cooked again before it's eaten, the presence of pathogens causes special concern. 14.4 percent of the 369 domestic samples of processed seafood were rated "Class 3"--enough pathogens were present to enable FDA to take official action, (e.g., a recall.) Crabmeat was contaminated frequently; 28.8 percent of the 165 samples were rated Class 3; 10.2 percent of the domestic 118 cooked shrimp samples also were actionable. Overall, the imports fared slightly better with 11.1 percent of the samples falling in the Class 3 category. The types of pathogens found included Listeria monocytogenes, vibrio cholera and E. coli. (See Chart C).

At the same FDA meeting, Richard Ronk, Acting Director of FDA's Center for Food Safety and Applied Nutrition explained that certain seafood companies do not follow good manufacturing practices, which exacerbates contamination problems. He said:

This problem of microbial contamination must be brought under control. It is widely recognized that microorganisms readily adapt to changing environments...It is well documented that certain segments of the seafood industry are not conforming to current good manufacturing practices in handling their products. Cross-contamination of raw and processed products and improper storage temperatures are examples of the problems mentioned today which need to be addressed by the seafood industry. (Source: Prepared; text of Mr. Ronk's Oral Remarks, National Seafood meeting, December 16, 1988, Washington, DC).

Also at the National Seafood Meeting, Ron McKay, Assistant Administrator, Food and Dairy Division of Oregon's Department of Agriculture, described how his department's investigation in 1987 of 17 Oregon seafood processing plants showed that even in this modern age, seafood plants are still using horse and buggy technology that threatens the public's health. Mr. McKay gave examples with graphic slides of unhealthful manufacturing practices. Unfortunately, these industry practices are not unique to these locations. Some included:

-- trash dumpsters without covers located outside a plant on its landing area. Seagulls were constantly attracted to the garbage. Their excrement littered the area on which seafood was delivered in open crates.

-- wooden crates and totes which cannot be properly sanitized were used without plastic liners to hold raw and then finished cooked product.

-- workers entering a plant walked through raw seafood juices before entering processing area and the firm did not provide a foot bath to cleanse their shoes.

The Oregon Agriculture Department made recommendations to these plants for sanitation improvements based on the HACCP approach.

Contamination of Seafood from Polluted Waterways

Pesticides and other chemical compounds which are present in waterways because of industrial and municipal dumping, agricultural run-off, and application of pesticides to marshes and shorelines pose a very real hazard to public health.

These chemical residues resist degradation, are incorporated into phytoplankton which is the first link in the food chain, and become concentrated in the tissues of fish and shellfish consumed by humans. Many of these residues present long term health risks to consumers. Some have been linked to cancer and other adverse health effects.

Even the limited data available on chemical contamination of fish demonstrates that toxins are commonplace in the seafood we eat. **Of all the domestic food samples collected and analyzed by FDA between 1979 and 1985, including vegetables and dairy products, fish had the highest percent of samples containing illegal residues, 5.2 percent**, whereas the market basket average was 2.9 percent. (Source: U.S. General Accounting Office, "Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues", October 1986 at 27. According to the report, .7 percent of fruits and fruit products contained illegal residues and 3.7 percent of leafy and other vegetables were similarly contaminated.)

In 1987, FDA tested only 711 samples (total for both domestic and imported) for pesticide residues. In those samples, the agency found that 73 percent of the domestic seafood samples and 22 percent of the imported ones had pesticide residues.

The metals most frequently associated with residues in fish and shellfish are mercury, lead, cadmium and arsenic. Of these, mercury has probably received the most public attention because elevated levels of mercury residues were discovered in many fish in the early 1970's when mercury was widely used in pesticides. Today, the primary use for mercury is the manufacture of batteries, paints and industrial instruments. Most mercury accumulated in fish tissues is in the form of methyl mercury, which is readily absorbed by the intestine in man and is the most toxic form of mercury. Large fish such as tuna, shark, salmon, and king mackerel usually have the highest mercury levels. In humans, excess levels lead to loss of appetite, birth defects, central nervous system damage and kidney damage.

Another group of contaminants, the chlorinated hydrocarbons, such as polychlorinated biphenyls (PCB's) DDT, and Dioxin, are the result of industrial pollution and pesticide run-off. These chemicals contaminate many fresh, brackish and coastal waters. PCB's are actually a group of more than 200 similar chemical compounds. From the 1930's to the mid-1970's, they were extensively used in industry as insulating fluids and coolants because they are extremely resistant to degradation. In 1977, manufacture of PCB's was banned in the U.S. because of concerns about long-range chronic health effects. PCB's are widespread in the environment and are frequently present in river and marine sediments as well as in the fatty tissues of fish.

State sportfishing advisories also give some indication for toxic hazards in fish. New York, for example, has closed some waterways to commercial fishing and has issued health advisories against sportfishing in areas because of chemical contamination. **A New York State Department of Health fishing advisory recommends eating no more than one meal per week of half a pound of fish taken from any water in the state.** The state also in April 1986 banned commercial fishing for striped bass in all New York waters. This ban was due to the fact that the DEC sampled 444 striped bass during the 1985 season, and almost all were contaminated with more than 2 ppm of PCB's, the FDA tolerance. A 1988 investigation by EPA into the public health impact of consumption of seafood from Quincy Bay, Massachusetts (known as the "flounder capital" of the world) showed that seafood can pose a serious risk of cancer. The risk estimates for the seafood were significantly higher than those estimated for consumption of other foods suspected to pose cancer risk (i.e.: with diet soda saccharin, with peanut butter aflatoxin). In particular, EPA found that "the estimated incremental risk (of cancer over a lifetime) (plausible upper bound) for the hypothetical Maximally Exposed Individual eating a mixed diet of Quincy seafood is about 50-100 times higher than the estimates for any of the other typical eating and drinking activities shown on the table. (See Chart D). The estimated risk (plausible upper bound) for just consumption of Quincy Bay winter flounder is about 10 times higher than the estimated for other typical eating and drinking activities." The other activities for comparisons included drinking milk, water, diet soda and eating peanut butter. (See Chart E). (Source: "Analysis of Risks from Consumption of Quincy Bay Fish and Shellfish," Prepared for U.S. EPA, Region I, May 1988 at 50-52).

Governmental Surveillance Inadequate

Given the serious potential health risks involved, it should be of deep concern to all of us that seafood gets hit-or-miss inspection at best under an inadequate patchwork of federal and state programs that address limited aspects of fish harvesting and processing. Federal seafood safety programs are fragmented, too often uncoordinated, and standards are often voluntary, absent entirely, or weakly monitored. State activities and budgets vary widely and do not compensate for federal weakness.

A 1986 report prepared for the National Marine Fisheries Service (NMFS), "Preliminary Analysis of a National Seafood Inspection Program" (Cooperative Agreement No. NA85AA-H-SK147) (hereinafter cited as NMFS Analysis) concluded that:

"**...present federal government efforts for ensuring the safety of U. S. seafood are minimal**. The FDA, which has authority for inspection of seafood in interstate commerce, carries out only limited surveillance inspection for most seafood and operates a National Shellfish Sanitation Program and a Canned Salmon Control Plan which are voluntary, cooperative programs. The voluntary inspection program of NMFS currently applies to only six percent of U.S. processing plants and an estimated 12 percent of seafood eaten by U. S. consumers." (at 2-2, highlighting added).

National Marine Fisheries Service

The National Marine Fisheries Service, (NMFS) a division of the Department of Commerce, operates a voluntary inspection and grading program, paid for by the corporate users. It is designed as a marketing tool to promote the marketing of fish products for the benefit of the domestic fisheries industry. Its grading service emphasizes uniformity of size, flavor, and freedom from blemishes. It is not a public health program. Despite the fact that per capita fish consumption has been rising steadily, the NMFS inspection service has been sharply decreasing. In 1987, NMFS' program covered about 11 percent of seafood consumed, down from about 18 percent in 1983.

Food and Drug Administration

The Food and Drug Administration (FDA) has authority to inspect seafood in interstate commerce under requirements of the Federal Food, Drug and Cosmetic Act. Yet, its surveillance is woefully scanty and too often responds to problems instead of preventing them. James Brennan, then Department of Commerce Assistant Administrator for Fisheries, testified earlier this summer that, "The current Food and Drug Administration inspection approach often focuses on problems after they occur."

According to FDA's own figures, the agency inspects only about one-quarter of the firms engaged in processing, shipping, packing, labeling, warehousing, and importing fish and/or seafood in a given year. And in no case does FDA inspect the facilities or operations of those vessels which process fish at sea.

In one of the most critical steps necessary to ensure the safety of our seafood supply - that is, the monitoring of chemical and microbial contamination of fish and shellfish - FDA's performance has been seriously inadequate. FDA, in cooperation with the Environmental Protection Agency (EPA), has established very few limits for toxins in seafood. **There is only one tolerance (compound limit) and only thirteen informal action levels for hazardous substances in fish (See Chart F), despite the fact that hundreds of chemicals may pose potential health threats.**

These weak standards do not give the public much protection. Only a tolerance is binding on the courts, the regulated industry and the agency. The action levels do not have the force of law. Thus, FDA is not required to initiate an enforcement action if an action level is exceeded.

In addition to lack of standards for chemical hazards, FDA tests only a minute percentage of fish for dangerous levels of residues. For example, **in 1987 the agency analyzed only 996 domestic and 628 imported seafood samples for pesticide and chemical residues. Meanwhile, Americans consumed over 3 billion pounds of fish in that same year!**

In stark contrast, the U.S. Department of Agriculture operates a more effective, statistically valid program for sampling meat for drug, pesticides and environmental contaminants. USDA's present routine monitoring provides a 95 percent probability of detecting a tested-for residue problem if it occurs in one percent of a slaughter population. In 1989, USDA expects to routinely monitor 44,000 samples. It will check approximately 24,800 biased samples for the surveillance part of the program. (Source: Speech of Dr. Lester M. Crawford, Administrator of the Food Safety and Inspection Service, USDA, before the Board of Inquiry of the European Parliament, Strausbourg, France, December 12, 1988.)

One example of the weakness of FDA's sampling program was revealed at a hearing held in California on February 10, 1986, by the House of Representative's Health and Environment Subcommittee on DDT pollution of Santa Monica Bay. The Montrose Chemical Company, which produced half the world's DDT before it was banned, discharged 400 to 600 pounds of DDT daily into the Santa Monica Bay for 26 years until 1972.

Several issues raised at the hearing suggest that the public may be exposed to dangerous levels of chemical residues from fish caught in southern California. The most striking evidence presented at the hearing were the results of a pilot study conducted by scientists in the L.A. Weekly, February 21, 1986. The researchers went to the markets throughout Los Angeles and bought over 150 fish caught locally. The researchers found that the fish had the highest overall concentrations of DDT of any seafood in the nation, and that several species such as ocean perch, white croaker, barracuda and mackerel had concentrations of both DDT and PCB's up to 50 times the national average, comparable to levels from areas that California health officials had closed due to the potential danger to public health.

FDA's own sampling for DDT residues in Los Angeles fish was minimal at best. At the hearing, David Steinman from Loma Linda University testified that in 1984-85, 57 million pounds of fish were landed in Los Angeles alone, but FDA had sampled only 30 fish through midyear 1985. FDA's enforcement activity in this area appears to have been grossly insufficient to guard against dangerously contaminated fish entering the marketplace.

National Shellfish Sanitation Program

Because shellfish filter and concentrate pathogenic microorganisms and toxic substances, and particularly because shellfish are eaten raw, they present a strong health risk. Yet, the one program which is supposed to protect the public from the health hazards associated with the consumption of shellfish has been described by the U.S. General Accounting Office as failing to meet its stated goals. The problems inherent in the Shellfish Sanitation Program (NSSP) include the fact that it is strictly voluntary in nature, that responsibility for NSSP is divided between FDA and the various states which choose to participate and the industry; that FDA has no enforcement authority to ensure compliance with the program's guidelines; and that the role of the states under the NSSP can often conflict with their economic interest in their state shellfish industry.

Because of the seriousness of risks from eating molluscan shellfish, Public Voice examined the effectiveness of this voluntary program in a recent report and found it lax and inadequate in protecting consumers. In this report, "Contaminated Catch: Holes in the Safety Net," we found that the current program lacked the necessary mandatory standards and enforcement authorities to prevent unnecessary consumer illnesses and even death. The unfortunate result is the risk of illness consumers face -- the Centers for Disease Control estimates that 1 in 250 consumers who eat raw shellfish will get ill.

FDA is the administrator of the NSSP. The agency reviews each participating state's program to determine whether it is in compliance with NSSP guidelines. FDA also publishes a list of interstate shellfish shippers certified by the states.

The FDA's annual report on the status of state shellfish sanitation programs for the year 1987 cited nine states out of 23 that participate for "major program deficiencies of public health significance." **Those states produced 54 percent of the U. S. shellfish harvest**. (See Chart G). Six of the states remained in "nonconformity" for the second consecutive year. Inadequately completed sanitary surveys of shellfish growing waters was a common cause for noncompliance.

The FDA report stated that "there is a growing concern that the improvements being made may be overshadowed or even negated by program deficiencies in the patrol and depuration program areas...." It also indicated the situation may worsen because "many states now judged to be marginally in program conformity will slip into nonconformity because program funding is not keeping abreast of program needs...."

Repeated attempts by Public Voice to obtain NSSP compliance figures for 1988 have met with resistance from FDA. We have been informed that FDA will no longer make public information on which states violate NSSP guidelines due to the fact that the states themselves were critical of such announcements by FDA.

A 1984 report by the General Accounting Office (GAO) entitled "Problems in Protecting Consumers from Illegally Harvested Shellfish" concluded that NSSP does not achieve its goal of ensuring that shellfish harvested in the United States is safe for human consumption. Among the weaknesses highlighted by GAO was that the voluntary nature of the program hinders its effectiveness. As stated in the NSSP's own Manual of Operations:

> The National Shellfish Sanitation Program is dependent entirely upon the States adopting the (Program's) recommended requirements and the cooperative and voluntary efforts of State regulatory agencies and the shellfish industry. (NSSP Manual of Operations, Part I, p. xiii)

According to the GAO report, "FDA cannot assure that members are adhering to program requirements." (GAO/HRD-84-36, p. ii) FDA's only available sanction is to withdraw endorsement of a state program, and this sanction has never been used and rarely even threatened.

The ability of the States to ensure that shellfish reaching the consumer is grown, harvested and processed in a sanitary manner was also criticized in the 1984 GAO report. Under the NSSP, shellfish shipping states are to adopt adequate laws and regulations for sanitary control of the shellfish industry, make sanitary surveys of growing areas and patrol restricted areas, inspect shellfish plants and conduct such other measures as are necessary.

However, according to State officials, state law enforcement agencies do not have sufficient staff or equipment to adequately enforce shellfish program requirements and patrol areas closed to shellfish harvesting. Further, fines assessed by state courts for illegal harvesting have generally been so low as to have little impact as a deterrent. And in addition, according to the GAO report, even when problems are uncovered by the states, contaminated shellfish often cannot be traced back to the growing areas from which they were harvested and to the persons who harvested them.

It is clear, then, from the findings cited above that neither FDA nor the States has the ability to carry out an effective shellfish monitoring program and the National Shellfish Sanitation Program cannot achieve its goal of assuring that shellfish harvested in the United States are safe for human consumption.

Mandatory Federal Inspection Needed

American consumers need protection from the health risks associated with eating fish and shellfish and they need it now. We commend you and the Committee for focusing on this critical gap in food safety protection and for your commitment to filling this gap with meaningful legislation. Public Voice, along with a national coalition of 35 consumer, environmental and health organizations, has called for a comprehensive, well-integrated mandatory federal seafood inspection program to address this problem.

We recognize that overall federal food safety policy is carried out by the Department of Agriculture, the Food and Drug Administration, the Environmental Protection Agency, and the Department of Commerce. Each of these agencies has an interest in seafood safety as well. As we begin the legislative process to correct a long-time gap in food protection, it is our hope that this process will be driven by an overriding interest in ensuring consumers a safe and wholesome seafood supply. It is critical that such legislation be viewed and designed as a public health, food safety program.

Any serious seafood safety proposal must address public health risks by setting strict food safety and sanitation standards and must be sufficiently detailed that it leaves no room for misinterpretation by the federal agencies in carrying it out. And it must be comprehensive, including at a minimum:

1) Application to all stages of processing, from harvesting to packing and transportation. Such legislation should provide for federal certification of fishing vessels, processing plants and distributors(including vehicles) based on strict sanitation, storage and handling requirements.
2) Authority for the Secretary of Agriculture to develop and administer a comprehensive, mandatory inspection program. The inspection activity should include unannounced, unrestricted spot checks of vessels, processing facilities and distributors.
3) A requirement that the Secretary of Health and Human Services set federal limits (standards) for chemical and microbial contaminants for fish and shellfish. At the heart of a truly effective modern federal seafood safety program must be the setting of health-based standards, or maximum permissible levels, for contaminants such as microbiological organisms and chemical residues allowed for fish and fish products. Not only is it important for legislation to mandate that standards be set, but history tells us it is also critical that such legislation spell out a precise timetable by which the agency must issue regulations setting contaminant standards.
4) A requirement that imported fish and fish products be part of an approved safety program that is equal to the program established by the Department of Agriculture for domestic seafood.
5) A clear process for the suspension of certificates for failure to comply with requirements.
6) Requirements for industry recordkeeping, including a system by which contaminated seafood can be traced back to its source.
7) Provision for the sampling and detention of products, suspension of operations or loss of license to operate if violations are found.
8) Employee protections to prohibit harassment of inspectors and discrimination against employees who carry out the requirements of the program.
9) Provision for a range of criminal and civil penalty options including fines up to $10,000 geared to the seriousness and frequency of violations.

We are happy to see that S.1245, which has been described by its sponsors as a starting point in the development of seafood safety legislation, addresses some of the elements which I have described. As Senate discussions progress, Public Voice hopes to continue working closely with you, Mr. Chairman, with Senate Majority Leader Mitchell and with all other members who share our interest in protecting U.S. consumers from unnecessary health hazards through a comprehensive, mandatory federal seafood safety program with public health-based standards for contaminants and a strong, effective inspection system. Unless legislation establishing a comprehensive, mandatory seafood inspection program is enacted and signed in this Congress, health conscious consumers who have turned to fish for a more healthful diet will be putting themselves at increasing risk of serious illness, even death.

On behalf of Public Voice and the Coalition for Mandatory Federal Fish Inspection, I congratulate you, Mr. Chairman, and members of the Committee for demonstrating your concern for ensuring the safety of the nation's seafood supply and for helping move the discussion of this critical issue forward. We offer whatever assistance we can provide in closing this serious gap in the federal food monitoring system.

[Charts A-G and Coalition for Mandatory Federal Fish Inspection follow:]

Chart A

Microbiological and Parasitic Hazards of Fish and Shellfish

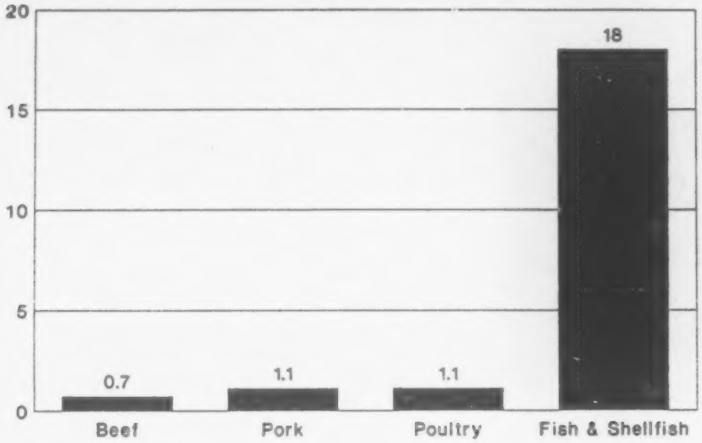
Fish Source	Toxins and Parasites	Disease Threat to Consumers	Symptoms
Most outbreaks caused by improperly preserved canned foods	C. botulinum	Botulism	Double vision, weakness, difficulty breathing; can cause paralysis by acting on the nervous system
Primarily bottom-dwelling shore fish caught near reefs; most commonly barracuda, red snapper, amberjack and grouper	Ciguatoxin	Ciguatera Fish Poisoning	Nausea, cramps, diarrhea, numbness of lips and tongue, reversal of hot and cold sensation, pain in extremities
Primarily tuna, mackerel, bonito and skipjack	Scombrotoxin	Scombroid Fish Poisoning	Flushing, headache, dizziness, burning of mouth and throat, bronchospasm, abdominal cramps, nausea, diarrhea
Pufferfish	Tetrodoxin	Fish Poisoning	Numbness, loss of perception, floating sensation
Mostly associated with eating raw or undercooked fish, such as sushi and sashimi	Anisakid-nematode	Anisakiadis	Stomach pains, nausea and vomiting; may penetrate stomach wall
Mollusks,[a] particularly those harvested from waters contaminated with sewage	Vibrio cholerae-01 bacteria	Cholera	Diarrhea; if case severe, can lead to dehydration and death

Chart A: (continued...)

Fish Source	Toxins and Parasites	Disease Threat to Consumers	Symptoms
Mollusks, particularly those harvested in summer months (bacteria multiplies more rapidly in warm water)	Vibrio cholerae non-01 bacteria	Gastroenteritis	Diarrhea, vomiting, fever, abdominal cramps
Mollusks (particularly if eaten raw)	Vibrio parahaemolyticus bacteria	Gastroenteritis	Abdominal pain, diarrhea, nausea, headache, fever
Mollusks	Vibrio vulnificus-bacteria	Septicemia	Abrupt onset of chills, fever and/or prostration (usually only people with liver disease are at risk)
Mollusks	Salmonella bacteria	Salmonellosis	Nausea, fever, headache, abdominal cramps, diarrhea
Mollusks (particularly if eaten raw)	Hepatitis-A virus	Hepatitus	Appetite loss, vomiting, diarrhea, and abdominal pain
Mollusks	Norwalk virus	Gastroenteritis	Nausea, vomiting, diarrhea, and abdominal pain
Shellfish	Gonyaulax	Paralytic shellfish poisoning	Tingling, numbness, burning sensation in the lips, tongue and face, muscular weakness, respiratory paralysis and gradual paralysis of extremities
Shellfish	Ptychodiscus	Neurtoxic shellfish poisoning	Tingling of extremities, reversal of hot and cold sensation, vomiting, diarrhea

Note a: Mollusks are a phylum of invertebrate animals including oysters, clams, mussels and snails.

CHART B: NUMBER OF OUTBREAKS PER BILLION POUNDS CONSUMED (1982-1986)



Source: CDC and USDA

CHART C

1988 FDA's Processed Seafood Analysis

	Number of Samples	Contaminated at level that could result in FDA Action (such as recall)
Domestic		
Crabmeat	165	28.8%
Cooked Shrimp	118	10.2%
Surimi	72	1.4%
Crawfish	10	20%
Nova Salmon	4	25%
	369	14.4%
Imported		
Crabmeat	94	16%
Cooked Shrimp	48	8.3%
Surimi	112	1.8%
Crawfish	10	50%
Lobster	6	16.7%
	270	11.1%

(Source: Kvenberg Oral Presentation, National Seafood Meeting, Dec. 16, 1988, Washington, DC).

CHART D

Upper Bound Estimated Life Time Cancer Risks From Consumption of Quincy Bay Seafood

	Maximally Exposed Individual		Typical Exposed Individual	
	Mixed Diet	Flounder	Mixed Diet	Mixed Diet
Clams	$2.1x10^{-4}$ (1%)	-	-	-
Flounder	$3.2x10^{-3}$ (14%)	$4.7x10^{-3}$ (100%)	$2.8x10^{-5}$ (33%)	$2.8x10^{-5}$ (2.2%)
Lobster Meat	$8.0x10^{-4}$ (3.4%)	-	$5.6x10^{-5}$ (67%)	$4.5x10^{-5}$ (3.5%)
Tomalley	$1.9x10^{-2}$ (82.6%)	-	-	$1.2x10^{-3}$ (92.3%)
Total Risk	$2.3x10^{-2}$	$4.7x10^{-3}$	$8.4x10^{-5}$	$1.3x10^{-3}$

Source: Analysis of Risks from Consumption of Quincy Bay Fish and Shellfish, Prepared for United States Environmental Protection Agency Region I, May 1988.

CHART E

Comparison of Estimated Lifetime Cancer Risks (Plausible Upper Limit)

Lifetime Cancer Risks From Eating and Drinking Activities	Estimated Lifetime Risks(a)
-Maximally Exposed Individual - mixed diet of Quincy Bay seafood	1.5 to 2.3×10^{-2}
-Maximally Exposed Individual - diet of Quincy Bay winter flounder	1.7 to 4.7×10^{-3}
-Typical Quincy area resident - mixed diet of Quincy Bay seafood, including lobster tomalley	9.2×10^{-4} to 1.3×10^{-3}
-Four Tablespoons peanut butter per day	5.6×10^{-4}
-One 12 1/2 ounce diet drink per day (6)	7.0×10^{-4}
-Average saccharin consumption in the United States	1.4×10^{-4}
-One pint milk per day (b)	1.4×10^{-4}
-Typical Quincy area resident - mixed diet of Quincy Bay seafood without lobster tomalley	4.7×10^{-5} to 8.4×10^{-5}
-Miami or New Orleans drinking water	7.0×10^{-5}
-1/2 lb. charcoal broiled steak per	2.1×10^{-7}

(cancer risk only; heart attack and other risks additional)

a) Except for Quincy Bay seafood consumption estimates for subpopulations, all other estimates are averaged over the whole population of the United States, assuming a 70 year lifetime.

b) Based on human data for aflatoxin carcinogenicity. Note that it is assumed that the measured aflatoxins are aflatoxin B, the most potent. If some corresponds to other aflatoxins, these estimated risks should be reduced.

Source: Analysis of Risks from Consumption of Quincy Bay Fish and Shellfish, Prepared for United States Environmental Protection Agency Region I, May 1988.

CHART F

FDA Action Levels for Poisonous or Delterious Chemical Substances in Seafood (Informal Standard)

Chemical	Seafood	Action Level (parts per million)
Aldrin	Fish & Shellfish	.3
Dieldrin	Fish & Shellfish	.3
Chlordane	Fish	.3
DDT, DDE and TDE (in adding the amounts of DDT, DDE, and TDE any of the three found below .2 ppm for fish is not counted)	Fish	5.0
Endrin	Fish & Shellfish	.3
Heptachlor	Fish & Shellfish	.3
Heptachlor Epoxide	Fish & Shellfish	.3
Kepone	Crabmeat, Fish & Shellfish	.4 .3
Mercury	Fish, Shellfish and Crustaceans	1.0
Mirex	Fish	.1
Toxaphene	Fish	5.0

FDA Tolerance Level (Formally Standard)

Chemical	Seafood	(Parts per million)
Polychlorinated Biphenyls (PBC's)	Fish	2.0

Chart G

Voluntary National Shellfish Sanitation Program
State Conformity With Guidelines Set By FDA – 1987

States	Commercial Landing (1,000 Lbs.)	Percent of US Total Landings	FDA Evaluation of Conformance of State Shellfish Sanitation Program with NSSP*
Alabama	19,596	2%	C
Alaska	156,607	13%	C
Arizona	NA	NA	NA
Arkansas	23	<1	NA
California	108,384	9%	NC
Colorado	NA	NA	NA
Connecticut	3,099	<1	NC
Delaware	4,290	<1	C
Florida	57,437	5%	C
Georgia	13,882	1%	C
Hawaii	1,094	<1	NA
Idaho	NA	NA	NA
Illinois	NA	NA	NA
Indiana	NA	NA	NA
Iowa	NA	NA	NA
Kansas	NA	NA	NA
Kentucky	90	<1	NA
Louisiana	189,350	16%	NC
Maine	46,651	4%	NC
Maryland	70,455	6%	C
Massachusetts	52,417	4%	NC
Michigan	NA	NA	NA
Minnesota	NA	NA	NA
Mississippi	14,397	1%	C
Missouri	NA	NA	NA
Montana	NA	NA	NA
Nebraska	NA	NA	NA
Nevada	NA	NA	NA
New Hampshire	1,475	<1	C
New Jersey	81,815	7%	NC
New Mexico	NA	NA	NA
New York	15,743	1%	NC
North Carolina	41,786	4%	C
North Dakota	NA	NA	NA
Ohio	NA	NA	NA
Oklahoma	1,069	<1	NA
Oregon	51,542	4%	NC
Pennsylvania	NA	NA	C
Rhode Island	28,053	2%	C

Voluntary National Shellfish Sanitation Program
State Conformity With Guidelines Set By FDA - 1987

States	Commercial Landing (1,000 Lbs.)	Percent of US Total Landings	FDA Evaluation of Conformance of State Shellfish Sanitation Program with NSSP*
South Carolina	11,040	1%	C
South Dakota	NA	NA	NA
Tennessee	2,054	<1	NA
Texas	106,369	9%	NC
Utah	NA	NA	NA
Vermont	NA	NA	NA
Virginia	69,561	6%	C
Washington	39,286	3%	C
West Virginia	NA	NA	NA
Wisconsin	NA	NA	NA
Wyoming	NA	NA	NA

C = Conforming

NA = Not Applicable

NC = Non-Conforming with National Shellfish Sanitation Program
Voluntary Guidelines Set by FDA

* Source = FDA Shellfish Sanitation Branch, "Report to the Interstate Shellfish Sanitation Conference: Status of State Shellfish Sanitation Program, 1987."

COALITION FOR MANDATORY FEDERAL FISH INSPECTION

Public Voice for Food and Health Policy
Alaska Public Interest Research Group
American Council on Consumer Awareness
Americans for Democratic Action/Consumer Affairs Committee
Americans for Safe Food
Arizona Consumers Council
Consumer Education and Protection Association of Kansans, Inc.
Center for Science in the Public Interest
Concern, Inc.
Concerned Consumers League
Consumer Action
Consumer Federation of America
Detroit Consumer Affairs Department
Earth Keep
Empire State Consumer Association
Environmental Action
Food and Water
Friends of the Earth
Gray Panthers of San Francisco
Harlem Consumer Education Council, Inc.
Human Environment Center
Idaho Consumer Affairs, Inc.
Iowa Consumers League
Michigan Citizens Lobby
National African-American Consumer Organization
National Consumers League
Natural Resources Defense Council
NY City Department of Consumer Affairs
Oceanic Society
Physicians Comm. for Responsible Medicine
Public Citizen Congress Watch
Rhode Island Public Interest Research Group
The American Dietetic Association
Vermont Public Interest Research Group
Wisconsin Consumers League
Wisconsin Family Farm Defense Fund

as of 7/6/89

STATEMENT
OF
LEE J. WEDDIG
EXECUTIVE VICE PRESIDENT
NATIONAL FISHERIES INSTITUTE
TO THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

The National Fisheries Institue is very appreciative of the opportunity to discuss the issues related to seafood safety and inspection, and is pleased that so many Senators have co-sponsored the subject legislation which would establish a comprehensive inspection program for fishery products in the United States.

The issue of seafood inspection not new.

Twenty-two years ago, the late Senator Philip Hart spoke at the annual convention of the National Fisheries Institute and outlined his belief that there was need for a better seafood inspection program. Senator Hart subsequently introduced legislation which was investigated in hearings, actually passed the Senate, but did not make it into law.

At the time, the seafood industry was struggling. The Soviet and other foreign fishing fleets were decimating our resources; the Catholic Church had just changed its dietary rules, allowing meat to be eaten on Fridays; and a well publicized incident involving botulism in smoked Michigan whitefish had scared consumers.

A lot has changed since 1967. The Magnuson Fisheries Conservation and Management Act provided means in 1976 to control foreign and domestic fishing pressure on the resources. Fish has become an everyday, not a Friday, food, and the previously unknown potential of botulism in smoked fish is safeguarded by processing and handling procedures.

The most dramatic change since 1967 has been the growth of fish and shellfish in the American diet. In 1967, per capita consumption was 10.6 pounds edible weight. Last year it was 15 pounds, an increase of more than 46 percent. Even more significant is the growth of fresh and frozen products, as opposed to canned. Here the increase was from 5.8 to 9.6 pounds, a 65 percent increase.

For most consumers, fish and shellfish is no longer an occasional food, or special treat. Seafood is a full fledged every day choice of consumers, along with beef, pork and poultry. The public realizes that fish provide excellent nutrition...low fat, low cholesterol and easily digested proteins.

These characteristics, together with the unique tastes and flavors of properly prepared seafood, and the desire for variety, strongly suggest that seafood consumption will continue to grow.

Such growth is good for the country. Health experts advise that heart disease can be alleviated by dietary changes which include more fish. Improvements in public health have direct benefits for the country. Certainly, quality of life is improved with variety; and the nation's economy benefits from a vibrant primary industry which creates income and jobs from renewable natural resources.

These benefits will accrue in the future only if consumers have full confidence in the safety, wholesomeness, and integrity of fish and seafood products. The National Fisheries Institute believes this confidence could be jeopardized without establishment of an improved regulatory system which includes mandatory inspection. Establishing a new regulatory system which embodies mandatory inspection is particularly challenging because of the vast diversity of the seafood industry. But the outline of proposed legislation indicates the task can be accomplished.

Bringing the issue of seafood inspection to a successful conclusion is important to the country since the impact on the economy of the fish and seafood industry is far more extensive than most people realize. A recent study conducted by the National Fisheries Education and Research Foundation shows that direct, indirect and induced economic impacts attributable to fish and seafood exceed $80 billion annually. More than one million full-time equivalent jobs are generated. These are big numbers and reflect the myriad pathways on which fish products move from the dock to the dinner table. The study shows that consumers pay about $30 billion annually for fish and seafood with about two-thirds being consumed in restaurants and other food service establishments.

While many of the economic impacts occur in the metropolitan areas, since that is where the value of distribution and service is realized, most primary economic impacts are generated in rural areas where jobs are needed. Thus, the seafood industry has most in common with traditional agriculture. The rapid growth of aquaculture has been particularly useful in agriculture based-regions, by providing another important cash crop.

The seafood industry is also very trade dependent, for both markets and supplies. More than 3 billion pounds of product for the edible market worth $5.5 billion were imported last year. This was slightly greater than imports of meat and poultry in volume, but substantially higher in value. As for exports, fishery products soared in 1988, exceeding one billion pounds and $2.1 billion, making the U.S. the world's largest fish exporter. The value of fish exports exceeds that of meat and poultry.

It is evident that seafood is a major component of our nation's food supply-- a component important enough to the consumer and the economy that our ability to maintain the confidence of consumers here and overseas must be protected for the common good.

Of course, the fish and seafood industry at present is not without regulation. It is subject to the Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. These laws are enforced by the Food and Drug Administration. Enforcement includes plant and product inspections and port-of-entry inspections for imports. The extent of this enforcement activity varies, but it does exist and has been documented in such reports as the General Accounting Office study of August, 1988, on Seafood Safety and the responses of the FDA to questions raised by the Chairman of the House Subcommittee on Oversight and Investigations of the Energy and Commerce Committee.

Various states also enforce their laws relating to food safety. In respect to molluscan shellfish, the coastal state governments, in coordination with the FDA, operate the National Shellfish Sanitation Program. Finally, the U.S. Department of Commerce provides a for fee voluntary inspection and grading service under the Agricultural Marketing Act of 1946.

The actions of overseas governments also have a bearing on seafood safety. Such major supplier nations as Canada, Norway and Iceland, among others, have inspection programs specifically designed for fish and seafood.

The problem is not that there is no inspection system, but rather that the present system is inconsistent and incomplete and thus does not provide the level of assurance demanded by the public. A large part of the current demand that more be done to assure the safety of fish stems from concern over the marine environment which has suffered from decades of toxic substance discharge, substandard sewage treatment, oceanic sludge dumping, pesticide run-off, and oil spills. While there is little evidence to show that present levels of toxic chemicals in fish actually cause illness, there remains a nagging concern over the long-term impacts.

Examination of the data on actual illnesses and deaths attributable to seafood, and analysis of the data's meaning, do not show widespread problems. The GAO report and documentation by the National Marine Fisheries Service and the FDA attest to this. A larger study now in progress at the National Academy of Sciences can be expected to shed more light on the extent of real problems attributed to seafood as well as to offer recommendations on how these are to be corrected.

It does appear that the major sources of illness attributable to seafood are those caused by contaminated molluscan shellfish when eaten raw; by ciguatoxic reef fish, a problem confined primarily to our tropical island territories; and scombrotoxic fish, a problem unique to a certain class of fish in which histamine can build up if the product is mishandled.

It is important to note that the seafood products which make up virtually all of consumption exhibit an excellent record of safety. It is equally important to note that most of the actual cases are the result of natural environmental conditions, such as the ciguatoxic fish and some of the raw molluscan shellfish. Also, although many fish are caught recreationally, the impact of sports caught fish in the illness statistics is not known.

While the degree of risk of illness attributable to seafood can be debated, NFI believes that the regulatory system should be intensified in all areas in which any type of statistical evidence of illness exists. Certainly, a new regulatory scheme must specifically address the problems of ciguatoxin, scombrotoxin and the unique natural toxins, bacteria and viruses at times found in mollusks.

We do not wish to minimize or discount the problems currently affecting relatively small percentages of our products. However, our basic position is that a new system is needed to anticipate rather than react to problems. Such a proactive program is needed because of significant changes occurring in our industry. Included are:

- Emergence of new species of fish on the market from new areas of the world. One of the attributes of the industry is the variety provided by new products, orange roughy, dory, hoki to name a few.
- Emergence of processing operations in developing nations. Many products are now processed, some into ready-to-eat form in such far away places as Taiwan, Thailand, the Philippines. The present system provides no means of checking the sanitary and other procedures in these locations other than at the U.S. port of entry.
- Emergence of aquaculture as a major source of products. Farm-raised fish is reported to be the fastest growing sector of agriculture in the U.S. It also is booming in other parts of the world. Farming fish involves the use of medications and feeds which should be monitored.
- New processing technology. One of the contributors to per capita consumption increases has been the surimi based family of products. This involves high tech food science; many additional innovations such as the mixing of fish and animal proteins can be expected. But new technology also opens the door to new potential problems.
- Growth in fully processed, ready-to-eat seafood. Social changes which provide less time for traditional home cooked meals and a growing shortage of labor for food service operators are encouraging the development of more and more ready-to-eat, or heat-and-serve products. These provide value to the consumer. However, since they are eaten without further cooking, their preparation in a processing plant demands scrupulous attention to sanitation and avoidance of cross-contamination. Specific good manufacturing procedures must be developed and employed.
- Processing at sea. Many products are processed at sea, out of easy access by inspectors. A new system must address this type of operation.

- Recognition of new bacteria and viruses. It seems that scientists are learning rapidly about the pathogenicity of certain bacteria and virus. Listeria monocytogenes and vibrio vulnificus are two of the pathogens now under scrutiny. As more causative agents are discovered, or better defined, procedures and regulations will have to change.

- Continued environmental concerns. The persistent use of the oceans as a convenient disposal site is a major concern. Fish in certain areas will absorb trace amounts of various industrial and agricultural toxic substances. The presence of such substances in fish is not of short term significance. However, many health professionals are concerned that long-term exposure to these chemicals, even in trace amounts, constitutes undue risk to consumers. This concern poses real difficulties for the commercial industry, in that constant attention to the issue is raised by environmental and other groups seeking the very important and necessary changes in water quality

  recreational anglers about the long term risks of heavy practices. Health authorities are responsible to warn recreational anglers about the long term risks of heavy consumption of certain species caught in polluted waters. While commercial fishing is often prohibited in these waters, and the warnings have no relevance to commercial product, the widely publicized warnings are generalized and cause apprehension in the minds of consumers.

These concerns prompted the National Fisheries Institute in 1985 to revive legislative efforts to improve the seafood inspection system. Our decision came after extensive debate, since few in industry want to invite greater regulation.

Our Board, however, believed that the real problems, the perceived problems, concerns over economic violations of law fostered by rising demand, and the problems on the horizon could be addressed only by a strong governmental program. The decision was not accepted universally within the industry. Many plant operators feared the unknown and did not want to endorse a change in regulation without knowing what was being planned.

NFI's first action was to ask Congress to mandate the design of a seafood inspection system based on the Hazard Analysis Critical Control Point (HACCP) concept recommended by the National Academy of Sciences. The design of this seafood surveillance program has been underway for the past two years. It includes the National Academy of Sciences study referenced earlier.

The industry is contributing considerable time and effort to see that this study is completed as soon as possible, with hundreds of industry professionals devoting thousands of days in government workshops and meetings. This work must be completed.

We believe it will provide the integral mechanism for a new regulatory program. The HACCP concept is not new. It is already incorporated in the FDA's low-acid canned food regulations. Very simply, HACCP is a safety-quality assurance system that provides for monitoring of those steps in a processing operation which have the potential of causing hazards. A separate HACCP procedure must be established for each different processing operation, i.e., one for a cooked shrimp processor, another for breaded shrimp, and so on through the entire range of processes in the industry.

The procedure employed is to:

- Define the operational steps;
- Identify the hazards;
- Determine the preventive measures for each hazard;
- Identify monitoring procedures for the hazard preventive measure;
- Assign relative importance for the hazards;
- Define the critical control or monitoring points; and
- Identify the records necessary to assure compliance.

We believe that the HACCP systems should be mandated as the key regulatory tool of an improved inspection system and are pleased that the concept is included as an integral part of the legislation outlined by the Chairman. We also believe that the overall comprehensive seafood regulatory system should include the following elements:

- Certification of Plants. This would involve an initial inspection of facilities and procedures; in short, assurance that the facility has the capability of producing wholesome product. The facility requirements would have to be specific to the type of processing and species handled. Certification would involve a registry of plants.

In respect to the scope of the program, we believe it should be devoted primarily to processing plants and distribution centers. Vessels which conduct processing to the extent that product is packaged and ready to go to the consumer should be covered. As the system evolves, the administering agency will determine if and where there is need to expand regulation and inspection procedures to harvesting vessels. Rather than begin with this requirement, we think a practical approach would be to require a review of the legislation after several years operation with a specific requirement to the agency to provide to Congress a review of needs to include harvesting vessels.

- Surveillance of operations. This aspect would require HACCP procedures by the plant operator and inspection to verify plant adherence to these on an as needed basis by the designated authority. The intensity of this surveillance would vary according to the degree of risk involved in the process and the record of the operator.

- Surveillance of Imports. Foreign governments wishing to have products imported into the United States would be encouraged to establish regulatory programs which would provide assurance of compliance to U.S. regulations. The level of sophistication in these systems would be measured by site visits and port-of-entry monitoring. The question of inspecting imports is a difficult one due to the large number of countries which supply the market, their varying capabilities of government, and the dependence we have on the supplies. Many of the nations are in the third world and are dependent on the seafood trade. We believe the system initially must provide flexibility with the control point being the port-of-entry inspection process. Products from those nations with certified systems would be audited at the port-of -entry. Those from countries whose systems are in an evolutionary state would receive intensive port of entry examinations up to 100 percent , dependent on the type of product and prior record.

- Increased molluscan growing water monitoring and enforcement. The current shellfish program provides the base for improvements in this very important area. Additional research to improve the reliability of the system is needed as well as funding to the states for increased monitoring and enforcement.
- Toxic substance monitoring. While current levels of contamination due to industrial pollution have not had widespread impact on the safety of coastal and oceanic resources, there is a need for continual monitoring of the resources for toxic substance residues. This effort on both domestic and imported product would serve to trigger compliance efforts through the HACCP programs and port-of-entry inspections if and when the surveillance shows persistent presence of toxins at levels of concern.
- Economic violation enforcement. The inspection system should include monitoring for economic abuses. Under the present regulatory system, economic violations do not receive intensive enforcement efforts. Since certain economic violations can result in safety concerns, we believe there is need to provide increased enforcement capabilities in this area. Increased enforcement is necessary also to assure fair dealing and to overcome any lapse of consumers' confidence as to receiving what is being paid for.

In summary, we see an improved regulatory system combining a series of new or expanded inspection and self monitoring efforts. We note that most of these concepts are included in the legislative outline.

This proposed system should be designed to meet unique concerns of seafood. It would be different than the carcass-by-carcass examinations of meat and poultry, and certainly different than regulatory systems for dairy products and other foods. Its establishment is a large task, one which will require a phase-in for both the industry and government.

The government agency chosen to establish such a system will face a very challenging task. The harvest and marketing of live lobsters is far different than the processing of Alaska pollock into imitation crab meat. Fish smoking requires a different code of practice than marketing fresh haddock fillets, and on and on. Government-to-government understandings must be reached with more than 80 foreign governments. The number of import shipments exceeds 160,000 annually at scores of ports of entry--all the way from northern Minnesota and Michigan to Nogales, Arizona, as well as the more readily expected seaports. There is need for rapid response. Perishable products cannot wait. And a single container of lobster tails, as an example, can have a value in excess of one half million dollars. Undue delays are very expensive. The plants are very often in remote locations and are often small and seasonal.

There are three federal agencies which could be given the seafood inspection task--the Food and Drug Administration; the Department of Commerce; and the Department of Agriculture. Each of these agencies offers strengths and each has some weaknesses. The Food and Drug Administration already has much of the legal authority needed. It has impressive credentials and expertise in the fields of microbiology, virology, parasitology and so on. It already inspects foods at the ports of entry and administers the National Shellfish Sanitation program. It also works closely with state health agencies.

On the negative side, FDA's other responsibilities are expanding and it has had difficulty in obtaining funding to fulfill them. Its matrix type of organization may be inconsistent with a dedicated program. It seems to operate in a crisis mode and lacks an overseas capability in food inspection. In these circumstances, a dedicated large seafood program could create an imbalance with FDA's other functions.

The Department of Commerce has impressive fishery expertise in the National Marine Fisheries Service. It has a core group of inspectors, some laboratories and standard setting procedures. It has daily contact with the industry. It has some authority to enforce foreign and state fish laws and is the federal fishery resource management agency.

On the other hand, the Department of Commerce also has taken on expanded responsibilities and obligations to protect species and manage fisheries. The Department's responsibilities and the Fisheries Conservation and Management Act are all consuming. Resource assessment needs are growing. Habitat protection is not keeping pace.

We are concerned whether these basic responsibilities would be threatened if the agency were to also take on the difficult assignment of mandatory inspection.

The Department of Agriculture has over 80 year's experience in food safety. It has the managerial infrastructure in place to handle large scale programs. It has respected scientific .pa capabilities and the confidence of consumers. It also has the lead federal role in aquaculture, which is a rapidly growing source of supply. USDA has established ties to overseas governments through its present inspection program and is heavily involved in export enhancement. A new large-scale program would not be out of proportion to the rest of the agency.

Negatively, USDA lacks extensive experience with fish. A fish program might be overwhelmed by meat and poultry activities. The idea of continuous inspection may be so ingrained in the USDA that a HACCP program may not work. USDA has no tie to the management of wild stocks of fish. The National Fisheries Institute in early discussions of the issue came to the conclusion that the most logical agency was the Department of Agriculture, with the assumption that the existing USDC inspection program would become a part of USDA. There are several reasons for this conclusion, but the most important ones were USDA's experience with large-scale operations in the field and its overseas capabilities. We are pleased that the Agriculture Committee apparently agrees with this conclusion.

In this statement we noted several times the need for ties to resource management. By this we mean the ability to prohibit commercial fishing in areas or for species which fail to pass muster with toxic substance residue tolerances. The concept is not new. Presently, molluscan shellfish safety is assured by monitoring and regulating shellfish growing waters. The same approach is used for some finfish at the state level.

We believe that controlling harvests is an effective way of achieving compliance to environmental contaminant tolerances. Once fish are caught, it is usually economically prohibitive to separate fish in compliance from those with excess residues. Accordingly, when problems are identified, harvest restrictions should be imposed. Again, we note with approval that this concept is included in the legislation's outline.

The question of financing a program must be addressed. It is our strong opinion that since appropriated funds are being used to provide the inspection system for meat and poultry, simple fairness dictates that appropriated funds be used for fish inspection. Seafood competes with meat and poultry in the market. Presently, those packers who utilize the USDC voluntary inspection service operate at a disadvantage since they incur heavy costs not borne by their competitors. The industry recognizes that the move to more intense regulation will not be simple or painless. But, the record shows that the U.S. fish and seafood industry has matured greatly since the time Senator Hart first broached the subject of inspection more than 20 years ago.

The very introduction of legislation in the past caused a reexamination of practices in the industry with resulting improvements in quality and wholesomeness. These improvements have contributed to the growth the industry has achieved. We believe that it's time to resolve this issue and institute a new mandatory seafood inspection program.

PREPARED STATEMENT OF THE AMERICAN MEAT INSTITUTE (AMI), SUBMITTED BY C. MANLY MOLPUS, PRESIDENT AND CEO, AMERICAN MEAT INSTITUTE, ARLINGTON, VA

Mr. Chairman, the American Meat Institute (AMI) is the national trade association representing over 450 meat packers and processors. Our members slaughter and process over 80 percent of the meat products produced in the United States. AMI appreciates this opportunity to share with the committee our views on S. 1245, "The Federal Fish Inspection Act."

Seafood and seafood products are one of the last protein sources in the American diet that remain largely uninspected. In fact, less than 10 percent of the fish, shellfish and related fish products consumed in the United States are inspected to any degree by the Federal Government. In 1988 per capita consumption of fish reached nearly 15 pounds—an increase of well over 46 percent since 1986.

We believe the time has come to seriously consider the merits of requiring all seafood and seafood products to be federally inspected to ensure consumer health and safety.

AMI was first established shortly after the Federal Meat Inspection Act (FMIA) was passed in 1906. Since that time, our members' plants and products have been under continuous USDA inspection. Without a doubt, we consider the USDA's Food Safety and Inspection Service (FSIS) to be the premier food inspection agency in the Federal Government today. We support efforts to make USDA the lead department for seafood inspection. No other department or agency in the government has the history, manpower, infrastructure, management capacity, international presence and consumer recognition as an inspector of food to handle the job.

Given USDA's resources and experience, Congress would do well to accord USDA considerable latitude in designing a workable seafood inspection program.

Should USDA ultimately end up with the seafood inspection program, one of the most important concerns for our members is to protect the integrity of the USDA "inspected and passed" legend. Whatever system of inspection is finally adopted for seafood, it must provide the consumer with the same safety assurances they currently receive under the Federal meat and poultry inspection program. To do otherwise would be inherently unfair to the consumer, to the meat and poultry producer, and to the food processor.

Another one of our concerns with the fish inspection proposal is cost. AMI and its members are opposed to funding the seafood inspection program through user fees. Seafood inspection, like meat and poultry, is a public health and safety program that would benefit the consumer. As such, it should be paid for out of general revenue funds and not user fees.

We have seen projected costs of the program ranging anywhere from $80 million to $125 million a year. These funds should be in addition to current funds expended for meat and poultry inspection if we are to maintain the credibility of all three inspection programs. Establishing the program in USDA will ensure the least additional cost because of the resources, expertise and experience already lodged there. We would, of course, be extremely concerned if FSIS programs for meat and poultry were to be adversely affected because of the introduction of a new inspection program for fish.

AMI has reviewed every inspection bill introduced and every draft seafood inspection bill that is currently pending. Without exception, all call for a system of inspection that employs the hazard analysis critical control point program, better known by the acronym HACCP.

A 1988 study published by the International Commission on Microbiological Specifications for Foods (ICMSF) entitled *HACCP in Microbiological Safety and Quality* aptly describes a HACCP system as ". . . a systematic approach to hazard identification, assessment and control. The system offers a rational approach to the control of microbiological hazards in foods, avoids the many weaknesses inherent in the inspectional approach and avoids the shortcomings of reliance on microbiological testing." These HACCP programs work equally well for other hazards, such as physical and chemical contamination.

The HACCP system, as defined in the study, is comprised of these steps: (1) Identification of hazards and assessment of severity of these hazards and their risks; (2) determination of critical control points at which identified hazards can be controlled; (3) specification of criteria that indicate whether an operation is under control at a particular critical control point; (4) establishment and implementation of procedures to monitor each critical control point to check that it is under control; (5) taking whatever corrective action is necessary when the monitoring results indicate that a particular critical control point is not under control; and (6) verification to ensure the HACCP system is working.

By focusing attention on those factors that directly affect the safety and quality of a food, USDA, by employing a HACCP based inspection system, could conserve limited inspection resources. By directing attention to the control of key factors that affect safety and quality throughout the food chain, government inspectors, producers, processors and consumers can all be assured that the desired levels of safety and quality have been met. If it is determined that a food is being produced, processed and used in accordance with the HACCP system, there is a high degree of assurance that it will meet end-user needs and expectations.

In short, Mr. Chairman, you cannot inspect quality into a product. The focus needs to be on the manufacturing process rather than dealing with the finished product. It is impossible for any government agency to test 100 percent of the products being inspected, but we can devise an inspection system to monitor 100 percent of the critical control points of a processing operation.

In 1986, AMI sought and won congressional approval for the Processed Product Inspection Improvement Act (PPIIA). One of the primary reasons we felt the industry could effectively operate without continuous, on-site USDA inspection system was because the meat processing industry is increasingly embracing the HACCP approach. Our companies build quality and safety into their products from the raw materials to the finished product. To do otherwise would spell economic disaster and business failure. We continue to feel that the HACCP system, utilized properly, can assure the consumer of the safest and highest quality product.

Historically, USDA's inspection emphasis has focused on animal health via ante- and post-mortem inspection of animals. The primary concern was to keep meat from diseased animals out of the food channels and to ensure that slaughter and meat processing operations were performed under sanitary conditions. Unfortunately today, most foodborne illnesses associated with animal products come from microorganisms not detected by the human eye. Continuous inspection through sight, smell and touch does little to prevent microbiological contamination.

USDA must redesign the inspection system to meet the challenges of human health and safety today. An inspection system based on monitoring and verifying a company's HACCP system will more adequately protect human health. USDA has embarked on an aggressive program to implement HACCP based inspection systems in meat and poultry plants.

As an aside, we find it very interesting that a number of interest groups have embraced the concept of HACCP for fish inspection when earlier this year they condemned USDA for designing a HACCP inspection system for meat. In several hearings on seafood inspection, some consumer groups have called for setting microbiological standards for seafood. AMI believes this is not the way to assure safe products. If Congress were to require USDA to set microbiological standards for seafood the only means USDA would have to ensure compliance would be through a microbiological testing program. It is the consensus of the scientific community that the use of testing to control microbiological hazards has serious limitations. Even the National Advisory Committee on Microbiological Criteria for Foods has not recommended this approach. Some serious limitations of this type of testing are: (1) the problem of sampling and examining a sufficient number of units to obtain meaningful information on the microbiological status of a batch of food; (2) time constraints—microbiological testing may take days—and the costs to obtain the results; and (3) microbiological testing of products only identifies effects and rarely identifies or controls causes.

The only way to control microbiological organisms successfully is by controlling the manufacturing process. Congress should not attempt to set risk levels. Experience has shown that the level of risk from a microorganism varies with conditions of the individual. To try to set an acceptable level or number of organisms that are permissible on a seafood product would be next to impossible. Fish, like meat and poultry products, is by its very nature subject to the presence of microorganisms. Trying to determine safe levels of these naturally occurring organisms would be next to impossible. We must all acknowledge there is some inherent risk involved in our foods today. Microorganisms will continue to exist on meat, poultry and fish and the only way to control or manage that risk is through the processing system, not through the inspection system.

In our way of thinking, microbiological standard-setting will give the consumer a false sense of security. It cannot and will not protect the consumer. Fish, meat and poultry are perishable products that need to be handled carefully. Short of sterilization, it is impossible to provide consumers with products totally void of microbiological contaminants. Yet, sterilization is not necessary for human health protection or even a desirable objective.

Another feature of many of the bills currently proposed for fish inspection is the concept of civil penalties for violations of the act. AMI questions this approach. Under current law, the Secretary has at his disposal a number of remedies to prevent noncompliance with the act. The Secretary has the authority to detain or condemn product; to request a recall; to seek criminal penalties for violations of the act; and, more importantly, to refuse inspection, thereby forcing an operation to close. It is hard to see why adding civil penalties will make it any more compelling for someone not to comply with the law.

If the committee feels the Secretary's authority to protect consumers is lacking, perhaps it may want to give the Secretary injunctive authority in the Federal courts to prevent noncompliance. This would give the Secretary ample opportunity to move expeditiously against an individual or company whose violation may endanger human health and safety.

Once again Mr. Chairman, thank you for providing AMI with this opportunity to make our comments for the record.